



**Australian Government**

**Department of Health**



# Schedule of Pharmaceutical Benefits

**Effective 1 December 2017**

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

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# Contents

<b>Fees, Patient Contributions and Safety Net Thresholds</b> .....	<b>1</b>
<b>Summary of Changes</b> .....	<b>2</b>
<b>About the Schedule</b> .....	<b>15</b>
Symbols and Abbreviations Used in the Schedule .....	15
Restricted Benefits .....	16
<b>Guidelines and General Statements</b> .....	<b>17</b>
General Statement for Lipid-Lowering Drugs .....	17
General Statement for Drugs for the Treatment of Hepatitis C.....	19
<b>Pharmaceutical Benefits Schedules</b> .....	<b>21</b>
Prescriber Bag .....	22
General Pharmaceutical Benefits .....	27
Palliative Care .....	756
Highly Specialised Drugs Program (Private Hospital) .....	769
Highly Specialised Drugs Program (Public Hospital).....	1003
Highly Specialised Drugs Program (Community Access).....	1239
Botulinum Toxin Program.....	1260
Growth Hormone Program .....	1268
IVF Treatment Program.....	1543
Opiate Dependence Treatment Program .....	1549
Repatriation Pharmaceutical Benefits Scheme .....	1552
<b>Extemporaneously Prepared Benefits</b> .....	<b>1606</b>
Drug Tariff .....	1607
Container Prices.....	1610
Standard Formula Preparations .....	1611
Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits .....	1612
<b>Index of Manufacturers' Code</b> .....	<b>1613</b>
<b>Generic/Proprietary Index</b> .....	<b>1615</b>



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# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 December 2017 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.15
	Dangerous drug fee	\$3.01
	Extemporaneously-prepared	\$9.19
	Allowable additional patient charge*	\$4.38
Additional Fees (for safety net prices):	Ready-prepared	\$1.21
	Extemporaneously-prepared	\$1.57
Patient Co-payments:	General	\$38.80
	Concessional	\$6.30
Safety Net Thresholds:	General	\$1494.90
	Concessional	\$378.00
Safety Net Card Issue Fee:		\$9.73

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

# Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 December 2017. The Schedule is updated on the first day of each month and is available on the internet at [www.pbs.gov.au](http://www.pbs.gov.au).

## Prescriber Bag

### Additions

#### Addition – Brand

- 3473T *HYOSCINE BUTYLBROMIDE SXP, XC* – **HYOSCINE BUTYLBROMIDE**, hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules
- 3496B *Salbutamol AN, JU* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules
- 3497C *Salbutamol AN, JU* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

#### Addition – Equivalence Indicator

- 3473T *Buscopan, VZ* – **HYOSCINE BUTYLBROMIDE**, hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

## General Pharmaceutical Benefits

### Additions

#### Addition – Item

- 11206T **ABIRATERONE**, abiraterone acetate 500 mg tablet, 60 (*Zytiga*)
- 11205R **ALPRAZOLAM**, alprazolam 250 microgram tablet, 10 (*Kalma 0.25*)
- 11197H **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)
- 11204Q **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)
- 11207W **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)
- 11223Q **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)
- 11198J **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)
- 11201M **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)
- 11202N **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys*)
- 11215G **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys*)
- 11218K **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys*)
- 11220M **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)
- 11221N **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys*)
- 11222P **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)
- 11196G **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Enbrel*)
- 11208X **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Enbrel*)
- 11211C **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys*)
- 11216H **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys*)
- 11217J **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys*)
- 11219L **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Enbrel*)
- 11224R **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Enbrel*)

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11225T	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys</i> )
11213E	<b>IBRUTINIB</b> , ibrutinib 140 mg capsule, 90 ( <i>Imbruvica</i> )
11210B	<b>MESALAZINE</b> , mesalazine 800 mg enteric tablet, 90 ( <i>Asacol</i> )
11209Y	<b>MILK POWDER LACTOSE INTOLERANCE FORMULA</b> , milk powder lactose intolerance formula powder for oral liquid, 900 g ( <i>S-26 Original LI</i> )
11200L	<b>VITAMINS, MINERALS AND TRACE ELEMENTS FORMULA</b> , vitamins, minerals and trace elements formula powder for oral liquid, 30 x 7 g sachets ( <i>Phlexy-Vits</i> )

**Addition – Brand**

2600W	<i>Allopurinol APOTEX, GX</i> – <b>ALLOPURINOL</b> , allopurinol 100 mg tablet, 200
2604C	<i>Allopurinol APOTEX, GX</i> – <b>ALLOPURINOL</b> , allopurinol 300 mg tablet, 60
11187T	<i>Kalma 0.5, AF</i> – <b>ALPRAZOLAM</b> , alprazolam 500 microgram tablet, 10
11186R	<i>Kalma 1, AF</i> – <b>ALPRAZOLAM</b> , alprazolam 1 mg tablet, 10
8594H	<i>Pharmacor Amisulpride, CR</i> – <b>AMISULPRIDE</b> , amisulpride 100 mg tablet, 30
8595J	<i>Pharmacor Amisulpride, CR</i> – <b>AMISULPRIDE</b> , amisulpride 200 mg tablet, 60
8596K	<i>Pharmacor Amisulpride, CR</i> – <b>AMISULPRIDE</b> , amisulpride 400 mg tablet, 60
1891M	<i>AMOXICLAV AMNEAL 500/125, ED</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10
5008N	<i>AMOXICLAV AMNEAL 500/125, ED</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10
5006L	<i>AMOXICLAV AMNEAL 875/125, ED</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8254K	<i>AMOXICLAV AMNEAL 875/125, ED</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8213G	<i>Pharmacor Atorvastatin, CR</i> – <b>ATORVASTATIN</b> , atorvastatin 10 mg tablet, 30
9230T	<i>Pharmacor Atorvastatin, CR</i> – <b>ATORVASTATIN</b> , atorvastatin 10 mg tablet, 30
8214H	<i>Pharmacor Atorvastatin, CR</i> – <b>ATORVASTATIN</b> , atorvastatin 20 mg tablet, 30
9231W	<i>Pharmacor Atorvastatin, CR</i> – <b>ATORVASTATIN</b> , atorvastatin 20 mg tablet, 30
8215J	<i>Pharmacor Atorvastatin, CR</i> – <b>ATORVASTATIN</b> , atorvastatin 40 mg tablet, 30
9232X	<i>Pharmacor Atorvastatin, CR</i> – <b>ATORVASTATIN</b> , atorvastatin 40 mg tablet, 30
8521L	<i>Pharmacor Atorvastatin, CR</i> – <b>ATORVASTATIN</b> , atorvastatin 80 mg tablet, 30
9233Y	<i>Pharmacor Atorvastatin, CR</i> – <b>ATORVASTATIN</b> , atorvastatin 80 mg tablet, 30
5551E	<i>Bimtop, QA</i> – <b>BIMATOPROST</b> , bimatoprost 0.03% eye drops, 3 mL
8620Q	<i>Bimtop, QA</i> – <b>BIMATOPROST</b> , bimatoprost 0.03% eye drops, 3 mL
5468T	<i>APO-Dutasteride, TX</i> – <b>DUTASTERIDE</b> , dutasteride 500 microgram capsule, 30
8700X	<i>Escitalopram Sandoz, HX</i> – <b>ESCITALOPRAM</b> , escitalopram 10 mg tablet, 28
8701Y	<i>Escitalopram Sandoz, HX</i> – <b>ESCITALOPRAM</b> , escitalopram 20 mg tablet, 28
1834M	<i>APO-Gabapentin, TX</i> – <b>GABAPENTIN</b> , gabapentin 300 mg capsule, 100
1835N	<i>APO-Gabapentin, TX</i> – <b>GABAPENTIN</b> , gabapentin 400 mg capsule, 100
8559L	<i>APO-Gabapentin, TX</i> – <b>GABAPENTIN</b> , gabapentin 600 mg tablet, 100
8389M	<i>APO-Gabapentin, TX</i> – <b>GABAPENTIN</b> , gabapentin 800 mg tablet, 100
2162T	<i>Cobal-B12, JU</i> – <b>HYDROXOCOBALAMIN</b> , hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules
2848X	<i>Sandoz Lamotrigine, HX</i> – <b>LAMOTRIGINE</b> , lamotrigine 25 mg tablet, 56
2849Y	<i>Sandoz Lamotrigine, HX</i> – <b>LAMOTRIGINE</b> , lamotrigine 50 mg tablet, 56
8170B	<i>PRYZEX, RW</i> – <b>OLANZAPINE</b> , olanzapine 2.5 mg tablet, 28
3381Y	<i>PRYZEX ODT, RW</i> – <b>OLANZAPINE</b> , OLANZAPINE Tablet 5 mg (orally disintegrating), 28
8185T	<i>PRYZEX, RW</i> – <b>OLANZAPINE</b> , olanzapine 5 mg tablet, 28

8186W *PRYZEX, RW* – **OLANZAPINE**, olanzapine 7.5 mg tablet, 28  
 3382B *PRYZEX ODT, RW* – **OLANZAPINE**, OLANZAPINE Tablet 10 mg (orally disintegrating), 28  
 8187X *PRYZEX, RW* – **OLANZAPINE**, olanzapine 10 mg tablet, 28  
 2000G *Salbutamol AN, JU* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules  
 2001H *Salbutamol AN, JU* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules  
 2285G *APO-Terbinafine, TX* – **TERBINAFINE**, terbinafine 250 mg tablet, 42  
 2804N *APO-Terbinafine, TX* – **TERBINAFINE**, terbinafine 250 mg tablet, 42  
 9070J *ZIPROX, RW* – **ZIPRASIDONE**, ziprasidone 20 mg capsule, 60  
 9071K *ZIPROX, RW* – **ZIPRASIDONE**, ziprasidone 40 mg capsule, 60  
 9072L *ZIPROX, RW* – **ZIPRASIDONE**, ziprasidone 60 mg capsule, 60  
 9073M *ZIPROX, RW* – **ZIPRASIDONE**, ziprasidone 80 mg capsule, 60

**Addition – Equivalence Indicator**

5468T *Avodart, GK* – **DUTASTERIDE**, dutasteride 500 microgram capsule, 30

**Addition – Note**

2130D **ALPRAZOLAM**, alprazolam 250 microgram tablet, 50 (*Alprax 0.25, Kalma 0.25*)  
 10896L **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)  
 10897M **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)  
 10893H **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL injection device (*Cosentyx*)  
 10898N **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL injection device (*Cosentyx*)  
 10901R **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (*Cosentyx*)

**Deletions**

**Deletion – Item**

10932J **AURANOFIN**, auranofin 3 mg tablet, 100 (*Ridaura*)  
 8283Y **MILK POWDER LACTOSE FREE FORMULA**, milk powder lactose free formula powder for oral liquid, 900 g (*S-26 LF*)  
 2989H **MILK POWDER LACTOSE FREE FORMULA PREDIGESTED**, milk powder lactose free formula predigested powder for oral liquid, 900 g (*Aptamil Gold+ De-Lact*)

**Deletion – Brand**

1884E *Chem mart Amoxicillin, CH* – **AMOXYCILLIN**, amoxicillin 250 mg capsule, 20  
 1884E *Terry White Chemists Amoxicillin, TW* – **AMOXYCILLIN**, amoxicillin 250 mg capsule, 20  
 3301R *Chem mart Amoxicillin, CH* – **AMOXYCILLIN**, amoxicillin 250 mg capsule, 20  
 3301R *Terry White Chemists Amoxicillin, TW* – **AMOXYCILLIN**, amoxicillin 250 mg capsule, 20  
 1889K *Chem mart Amoxicillin, CH* – **AMOXYCILLIN**, amoxicillin 500 mg capsule, 20  
 1889K *Terry White Chemists Amoxicillin, TW* – **AMOXYCILLIN**, amoxicillin 500 mg capsule, 20  
 3300Q *Chem mart Amoxicillin, CH* – **AMOXYCILLIN**, amoxicillin 500 mg capsule, 20  
 3300Q *Terry White Chemists Amoxicillin, TW* – **AMOXYCILLIN**, amoxicillin 500 mg capsule, 20  
 2729P *Chem mart Baclofen, CH* – **BACLOFEN**, baclofen 10 mg tablet, 100  
 2729P *Terry White Chemists Baclofen, TW* – **BACLOFEN**, baclofen 10 mg tablet, 100  
 2730Q *Chem mart Baclofen, CH* – **BACLOFEN**, baclofen 25 mg tablet, 100  
 2730Q *Terry White Chemists Baclofen, TW* – **BACLOFEN**, baclofen 25 mg tablet, 100  
 3094W *APO-Cephalexin, TX* – **CEPHALEXIN**, cephalexin 125 mg/5 mL powder for oral liquid, 100 mL  
 3094W *Chem mart Cephalexin, CH* – **CEPHALEXIN**, cephalexin 125 mg/5 mL powder for oral liquid, 100 mL  
 3094W *Terry White Chemists Cephalexin, TW* – **CEPHALEXIN**, cephalexin 125 mg/5 mL powder for oral liquid, 100 mL  
 3319Q *APO-Cephalexin, TX* – **CEPHALEXIN**, cephalexin 125 mg/5 mL powder for oral liquid, 100 mL

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3319Q Chem mart Cephalexin, CH – **CEPHALEXIN**, cephalexin 125 mg/5 mL powder for oral liquid, 100 mL  
3319Q Terry White Chemists Cephalexin, TW – **CEPHALEXIN**, cephalexin 125 mg/5 mL powder for oral liquid, 100 mL  
3095X APO-Cephalexin, TX – **CEPHALEXIN**, cephalexin 250 mg/5 mL powder for oral liquid, 100 mL  
3095X Chem mart Cephalexin, CH – **CEPHALEXIN**, cephalexin 250 mg/5 mL powder for oral liquid, 100 mL  
3095X Terry White Chemists Cephalexin, TW – **CEPHALEXIN**, cephalexin 250 mg/5 mL powder for oral liquid, 100 mL  
3320R APO-Cephalexin, TX – **CEPHALEXIN**, cephalexin 250 mg/5 mL powder for oral liquid, 100 mL  
3320R Chem mart Cephalexin, CH – **CEPHALEXIN**, cephalexin 250 mg/5 mL powder for oral liquid, 100 mL  
3320R Terry White Chemists Cephalexin, TW – **CEPHALEXIN**, cephalexin 250 mg/5 mL powder for oral liquid, 100 mL  
2591J Roaccutane, RO – **ISOTRETINOIN**, isotretinoin 10 mg capsule, 60  
8374R APO-Leflunomide, TX – **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30  
8375T APO-Leflunomide, TX – **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30  
8883M Avanza, MK – **MIRTAZAPINE**, mirtazapine 45 mg tablet, 30  
8355R Chem mart Telmisartan, CH – **TELMISARTAN**, telmisartan 40 mg tablet, 28  
8355R Terry White Chemists Telmisartan, TW – **TELMISARTAN**, telmisartan 40 mg tablet, 28  
8356T Chem mart Telmisartan, CH – **TELMISARTAN**, telmisartan 80 mg tablet, 28  
8356T Terry White Chemists Telmisartan, TW – **TELMISARTAN**, telmisartan 80 mg tablet, 28

**Deletion – Note**

5265D **FENTANYL**, fentanyl 12 microgram/hour patch, 5 (*Denpax*)  
5437E **FENTANYL**, fentanyl 12 microgram/hour patch, 5 (*Dutran 12, Fenpatch 12*)  
8878G **FENTANYL**, fentanyl 12 microgram/hour patch, 5 (*APO-Fentanyl, Durogesic 12, Fentanyl Sandoz*)  
5277R **FENTANYL**, fentanyl 25 microgram/hour patch, 5 (*Denpax*)  
5438F **FENTANYL**, fentanyl 25 microgram/hour patch, 5 (*Dutran 25, Fenpatch 25*)  
8891Y **FENTANYL**, fentanyl 25 microgram/hour patch, 5 (*APO-Fentanyl, Durogesic 25, Fentanyl Sandoz*)  
5278T **FENTANYL**, fentanyl 50 microgram/hour patch, 5 (*Denpax*)  
5279W **FENTANYL**, fentanyl 75 microgram/hour patch, 5 (*Denpax*)  
5439G **FENTANYL**, fentanyl 50 microgram/hour patch, 5 (*Dutran 50, Fenpatch 50*)  
8892B **FENTANYL**, fentanyl 50 microgram/hour patch, 5 (*APO-Fentanyl, Durogesic 50, Fentanyl Sandoz*)  
5280X **FENTANYL**, fentanyl 100 microgram/hour patch, 5 (*Denpax*)  
5440H **FENTANYL**, fentanyl 75 microgram/hour patch, 5 (*Dutran 75, Fenpatch 75*)  
8893C **FENTANYL**, fentanyl 75 microgram/hour patch, 5 (*APO-Fentanyl, Durogesic 75, Fentanyl Sandoz*)  
5441J **FENTANYL**, fentanyl 100 microgram/hour patch, 5 (*Dutran 100, Fenpatch 100*)  
8894D **FENTANYL**, fentanyl 100 microgram/hour patch, 5 (*APO-Fentanyl, Durogesic 100, Fentanyl Sandoz*)  
1024X **OLANZAPINE**, olanzapine 2.5 mg tablet, 28 (*Olanzapine generichealth 2.5*)  
8170B **OLANZAPINE**, olanzapine 2.5 mg tablet, 28 (*APO-Olanzapine, Chem mart Olanzapine, Olanzacor 2.5, Olanzapine AN, Olanzapine RBX, Olanzapine Sandoz, Olanzapine-DRLA, Ozin 2.5, PRYZEX, Terry White Chemists Olanzapine, Zypine, Zyprexa*)  
1037N **OLANZAPINE**, olanzapine 5 mg tablet, 28 (*Olanzapine generichealth 5*)  
3381Y **OLANZAPINE**, OLANZAPINE Tablet 5 mg (orally disintegrating), 28 (*APO-Olanzapine ODT, Olanzapine AN ODT, Olanzapine ODT generichealth 5, Olanzapine ODT-DRLA, Olanzapine Sandoz ODT 5, Ozin ODT 5, PRYZEX ODT*)  
8185T **OLANZAPINE**, olanzapine 5 mg tablet, 28 (*APO-Olanzapine, Chem mart Olanzapine, Olanzacor 5, Olanzapine AN, Olanzapine RBX, Olanzapine Sandoz, Olanzapine-DRLA, Ozin 5, PRYZEX, Terry White Chemists Olanzapine, Zypine, Zyprexa*)  
1041T **OLANZAPINE**, olanzapine 7.5 mg tablet, 28 (*Olanzapine generichealth 7.5*)  
8186W **OLANZAPINE**, olanzapine 7.5 mg tablet, 28 (*APO-Olanzapine, Chem mart Olanzapine, Olanzacor 7.5, Olanzapine AN, Olanzapine RBX, Olanzapine Sandoz, Olanzapine-DRLA, Ozin 7.5, PRYZEX, Terry White Chemists Olanzapine, Zypine, Zyprexa*)

1042W	<b>OLANZAPINE</b> , olanzapine 10 mg tablet, 28 ( <i>Olanzapine generichealth 10</i> )
3382B	<b>OLANZAPINE</b> , OLANZAPINE Tablet 10 mg (orally disintegrating), 28 ( <i>APO-Olanzapine ODT, Olanzapine AN ODT, Olanzapine ODT generichealth 10, Olanzapine ODT-DRLA, Olanzapine Sandoz ODT 10, Ozin ODT 10, PRYZEX ODT</i> )
8187X	<b>OLANZAPINE</b> , olanzapine 10 mg tablet, 28 ( <i>APO-Olanzapine, Chem mart Olanzapine, Olanzacor 10, Olanzapine AN, Olanzapine RBX, Olanzapine Sandoz, Olanzapine-DRLA, Ozin 10, PRYZEX, Terry White Chemists Olanzapine, Zypine, Zyprexa</i> )
3384D	<b>OLANZAPINE</b> , olanzapine 15 mg tablet, 28 ( <i>APO-Olanzapine ODT, Olanzapine AN ODT, Olanzapine Sandoz ODT 15, Ozin ODT 15</i> )
3385E	<b>OLANZAPINE</b> , olanzapine 20 mg tablet, 28 ( <i>APO-Olanzapine ODT, Olanzapine AN ODT, Olanzapine Sandoz ODT 20, Ozin ODT 20</i> )
8433W	<b>OLANZAPINE</b> , olanzapine 5 mg wafer, 28 ( <i>Zypine ODT, Zyprexa Zydys</i> )
8434X	<b>OLANZAPINE</b> , olanzapine 10 mg wafer, 28 ( <i>Zypine ODT, Zyprexa Zydys</i> )
8952E	<b>OLANZAPINE</b> , olanzapine 15 mg wafer, 28 ( <i>Zypine ODT, Zyprexa Zydys</i> )
8953F	<b>OLANZAPINE</b> , olanzapine 20 mg wafer, 28 ( <i>Zypine ODT, Zyprexa Zydys</i> )

## Alterations

### Alteration – Note

11068M	<b>ABATACEPT</b> , abatacept 125 mg/mL injection, 4 x 1 mL syringes ( <i>Orencia ClickJect</i> )
11092T	<b>ABATACEPT</b> , abatacept 125 mg/mL injection, 4 x 1 mL syringes ( <i>Orencia ClickJect</i> )
1220F	<b>ABATACEPT</b> , abatacept 125 mg/mL injection, 4 x 1 mL syringes ( <i>Orencia</i> )
1221G	<b>ABATACEPT</b> , abatacept 125 mg/mL injection, 4 x 1 mL syringes ( <i>Orencia</i> )
8737W	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes ( <i>Humira</i> )
8741C	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes ( <i>Humira</i> )
9033K	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes ( <i>Humira</i> )
9034L	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes ( <i>Humira</i> )
9077R	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes ( <i>Humira</i> )
9078T	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes ( <i>Humira</i> )
9099X	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges ( <i>Humira</i> )
9100Y	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges ( <i>Humira</i> )
9101B	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges ( <i>Humira</i> )
9102C	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges ( <i>Humira</i> )
9103D	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges ( <i>Humira</i> )
9104E	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges ( <i>Humira</i> )
9425C	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes ( <i>Humira</i> )
9426D	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges ( <i>Humira</i> )
9427E	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes ( <i>Humira</i> )
9428F	<b>ADALIMUMAB</b> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges ( <i>Humira</i> )
10137M	<b>CERTOLIZUMAB PEGOL</b> , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes ( <i>Cimzia</i> )
10238W	<b>CERTOLIZUMAB PEGOL</b> , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes ( <i>Cimzia</i> )
10904X	<b>CERTOLIZUMAB PEGOL</b> , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes ( <i>Cimzia</i> )
10905Y	<b>CERTOLIZUMAB PEGOL</b> , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes ( <i>Cimzia</i> )
10909E	<b>CERTOLIZUMAB PEGOL</b> , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes ( <i>Cimzia</i> )
3425G	<b>CERTOLIZUMAB PEGOL</b> , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes ( <i>Cimzia</i> )
8637N	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
8638P	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
8778B	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )

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8779C **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)

9035M **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)

9036N **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)

9037P **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)

9429G **ETANERCEPT**, etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (*Enbrel*)

9455P **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)

9456Q **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)

9457R **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)

9458T **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)

9459W **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)

9460X **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)

9461Y **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)

9462B **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)

9085E **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys, Enbrel*)

9086F **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys, Enbrel*)

9087G **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys, Enbrel*)

9088H **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys, Enbrel*)

9089J **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys, Enbrel*)

9090K **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys, Enbrel*)

9091L **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys, Enbrel*)

9431J **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys, Enbrel*)

3426H **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3427J **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3428K **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3429L **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3430M **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3431N **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3432P **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3433Q **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3434R **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3435T **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3436W **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

3437X **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)

11170X **IDELALISIB**, idelalisib 100 mg tablet, 60 (*Zydelig*)

11162L **IDELALISIB**, idelalisib 150 mg tablet, 60 (*Zydelig*)

11032P **IXEKIZUMAB**, ixekizumab 80 mg/mL injection, 2 x 1 mL injection devices (*Taltz*)

11033Q **IXEKIZUMAB**, ixekizumab 80 mg/mL injection, 2 x 1 mL injection devices (*Taltz*)

10425Q **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (*Cosentyx*)

10494H **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (*Cosentyx*)

10890E **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL injection device (*Cosentyx*)

10894J **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (*Cosentyx*)

10895K **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL injection device (*Cosentyx*)

10899P **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (*Cosentyx*)

10900Q **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL injection device (*Cosentyx*)

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10906B	<b>SECUKINUMAB</b> , secukinumab 150 mg/mL injection, 1 mL injection device ( <i>Cosentyx</i> )
10910F	<b>SECUKINUMAB</b> , secukinumab 150 mg/mL injection, 2 x 1 mL injection devices ( <i>Cosentyx</i> )
10951J	<b>TOCILIZUMAB</b> , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes ( <i>Actemra Subcutaneous Injection</i> )
10954M	<b>TOCILIZUMAB</b> , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes ( <i>Actemra Subcutaneous Injection</i> )
10511F	<b>TOFACITINIB</b> , tofacitinib 5 mg tablet, 56 ( <i>Xeljanz</i> )
10517M	<b>TOFACITINIB</b> , tofacitinib 5 mg tablet, 56 ( <i>Xeljanz</i> )
10767Q	<b>USTEKINUMAB</b> , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial ( <i>Stelara</i> )
10774C	<b>USTEKINUMAB</b> , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial ( <i>Stelara</i> )
9304Q	<b>USTEKINUMAB</b> , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial ( <i>Stelara</i> )
9305R	<b>USTEKINUMAB</b> , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial ( <i>Stelara</i> )

#### **Alteration – Restriction**

The following items have additions, deletions or alterations to restrictions.

8637N	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
8638P	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
8778B	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
8779C	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
9035M	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
9036N	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
9037P	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
9429G	<b>ETANERCEPT</b> , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack ( <i>Enbrel</i> )
9455P	<b>ETANERCEPT</b> , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 ( <i>Brenzys, Enbrel</i> )
9456Q	<b>ETANERCEPT</b> , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 ( <i>Brenzys, Enbrel</i> )
9457R	<b>ETANERCEPT</b> , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 ( <i>Brenzys, Enbrel</i> )
9458T	<b>ETANERCEPT</b> , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 ( <i>Brenzys, Enbrel</i> )
9459W	<b>ETANERCEPT</b> , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 ( <i>Brenzys, Enbrel</i> )
9460X	<b>ETANERCEPT</b> , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 ( <i>Brenzys, Enbrel</i> )
9461Y	<b>ETANERCEPT</b> , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 ( <i>Brenzys, Enbrel</i> )
9462B	<b>ETANERCEPT</b> , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 ( <i>Brenzys, Enbrel</i> )
9085E	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys, Enbrel</i> )
9086F	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys, Enbrel</i> )
9087G	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys, Enbrel</i> )
9088H	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys, Enbrel</i> )
9089J	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys, Enbrel</i> )
9090K	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys, Enbrel</i> )
9091L	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys, Enbrel</i> )
9431J	<b>ETANERCEPT</b> , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 ( <i>Brenzys, Enbrel</i> )
10958R	<b>EVOLOCUMAB</b> , evolocumab 140 mg/mL injection, 1 mL injection device ( <i>Repatha</i> )
1454M	<b>GOSERELIN</b> , goserelin 3.6 mg implant, 1 ( <i>Zoladex Implant</i> )
1976B	<b>ICATIBANT</b> , ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1 ( <i>Firazyr</i> )
11170X	<b>IDELALISIB</b> , idelalisib 100 mg tablet, 60 ( <i>Zydelig</i> )
11162L	<b>IDELALISIB</b> , idelalisib 150 mg tablet, 60 ( <i>Zydelig</i> )
2975N	<b>MILK POWDER LACTOSE FREE FORMULA PREDIGESTED</b> , milk powder lactose free formula predigested powder for oral liquid, 900 g ( <i>Aptamil Gold+ De-Lact</i> )
10899P	<b>SECUKINUMAB</b> , secukinumab 150 mg/mL injection, 2 x 1 mL injection devices ( <i>Cosentyx</i> )
10900Q	<b>SECUKINUMAB</b> , secukinumab 150 mg/mL injection, 1 mL injection device ( <i>Cosentyx</i> )
10901R	<b>SECUKINUMAB</b> , secukinumab 150 mg/mL injection, 2 x 1 mL injection devices ( <i>Cosentyx</i> )

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**Alteration – Manufacturer Code**

		<i>From</i>	<i>To</i>
3138E	<i>Clindamycin-Link</i> – <b>CLINDAMYCIN</b> , clindamycin 150 mg capsule, 24	LM	LI
5057E	<i>Clindamycin-Link</i> – <b>CLINDAMYCIN</b> , clindamycin 150 mg capsule, 24	LM	LI

**Advance Notices****1 January 2018****Deletion – Brand**

1411G	<i>add-ins, SB</i> – <b>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE</b> , AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1
1892N	<i>Augmentin, AS</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
5009P	<i>Augmentin, AS</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
1081X	<i>Atenolol RBX, RA</i> – <b>ATENOLOL</b> , atenolol 50 mg tablet, 30
10778G	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 500 mg capsule, 20
2655R	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 250 mg capsule, 20
3058Y	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 250 mg capsule, 20
3094W	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 125 mg/5 mL powder for oral liquid, 100 mL
3095X	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 250 mg/5 mL powder for oral liquid, 100 mL
3119E	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 500 mg capsule, 20
3317N	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 250 mg capsule, 20
3318P	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 500 mg capsule, 20
3319Q	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 125 mg/5 mL powder for oral liquid, 100 mL
3320R	<i>lalex, LN</i> – <b>CEPHALEXIN</b> , cephalexin 250 mg/5 mL powder for oral liquid, 100 mL
1127H	<i>Opticrom, SW</i> – <b>CROMOGLYCATE</b> , sodium cromoglycate 2% eye drops, 10 mL
5529B	<i>Opticrom, SW</i> – <b>CROMOGLYCATE</b> , sodium cromoglycate 2% eye drops, 10 mL
1512N	<i>Chem mart Hydroxychloroquine, CH</i> – <b>HYDROXYCHLOROQUINE</b> , hydroxychloroquine sulfate 200 mg tablet, 100
1512N	<i>Terry White Chemists Hydroxychloroquine, TW</i> – <b>HYDROXYCHLOROQUINE</b> , hydroxychloroquine sulfate 200 mg tablet, 100
2848X	<i>Lamidus, RA</i> – <b>LAMOTRIGINE</b> , lamotrigine 25 mg tablet, 56
2849Y	<i>Lamidus, RA</i> – <b>LAMOTRIGINE</b> , lamotrigine 50 mg tablet, 56
2850B	<i>Lamidus, RA</i> – <b>LAMOTRIGINE</b> , lamotrigine 100 mg tablet, 56
2851C	<i>Lamidus, RA</i> – <b>LAMOTRIGINE</b> , lamotrigine 200 mg tablet, 56
1956Y	<i>Memantine RBX, RA</i> – <b>MEMANTINE</b> , memantine hydrochloride 10 mg tablet, 56
2492E	<i>Memantine RBX, RA</i> – <b>MEMANTINE</b> , memantine hydrochloride 10 mg tablet, 56
2513G	<i>Memantine RBX, RA</i> – <b>MEMANTINE</b> , memantine hydrochloride 20 mg tablet, 28
9306T	<i>Memantine RBX, RA</i> – <b>MEMANTINE</b> , memantine hydrochloride 20 mg tablet, 28
2430X	<i>Metformin Ranbaxy, RA</i> – <b>METFORMIN</b> , metformin hydrochloride 500 mg tablet, 100
1821W	<i>Metronidazole Sandoz IV, SZ</i> – <b>METRONIDAZOLE</b> , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags
1832K	<i>Metronidazole Sandoz IV, SZ</i> – <b>METRONIDAZOLE</b> , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags
2341F	<i>Axiron, LY</i> – <b>TESTOSTERONE</b> , testosterone 2% (30 mg/actuation) solution, 60 actuations

## 1 February 2018

### Deletion – Brand

- 2878L *Intal Spincaps, EA* – **CROMOGLYCATE**, sodium cromoglycate 20 mg powder for inhalation, 100 capsules
- 8282X *S-26 LF, AS* – **MILK POWDER LACTOSE FREE FORMULA**, milk powder lactose free formula powder for oral liquid, 900 g
- 8864M *Exorex, GN* – **PREPARED COAL TAR**, prepared coal tar 1% w/w lotion, 100 mL
- 8526R *Metalyse, BY* – **TENECTEPLASE**, tenecteplase 8000 units (40 mg) injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack
- 8527T *Metalyse, BY* – **TENECTEPLASE**, tenecteplase 10 000 units (50 mg) injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack
- 2114G *Primoteston Depot, BN* – **TESTOSTERONE ENANTHATE**, testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes
- 10113G *Timentin, AS* – **TICARCILLIN + CLAVULANIC ACID**, ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial
- 10125X *Timentin, AS* – **TICARCILLIN + CLAVULANIC ACID**, ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial

## 1 March 2018

### Deletion – Brand

- 8973G *Actonel EC Combi, UA* – **RISEDRONATE (&) CALCIUM CARBONATE**, RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

## 1 May 2018

### Deletion – Brand

- 8974H *Actonel EC Combi D, UA* – **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**, RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

## Palliative Care

### Additions

#### Addition – Brand

- 5317W *HYOSCINE BUTYLBROMIDE SXP, XC* – **HYOSCINE BUTYLBROMIDE**, hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

#### Addition – Equivalence Indicator

- 5317W *Buscopan, VZ* – **HYOSCINE BUTYLBROMIDE**, hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

## Highly Specialised Drugs Program (Private Hospital)

### Deletions

#### Deletion – Item

- 10235Q **APOMORPHINE**, apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules (*Apomine*)

#### Deletion – Brand

- 6429J *APO-BOSENTAN, GX* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
- 6430K *APO-BOSENTAN, GX* – **BOSENTAN**, bosentan 125 mg tablet, 60

#### Deletion – Note

- 9685R **EPOETIN LAMBDA**, epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes (*Novicrit*)
- 9686T **EPOETIN LAMBDA**, epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes (*Novicrit*)
- 9687W **EPOETIN LAMBDA**, epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes (*Novicrit*)
- 9688X **EPOETIN LAMBDA**, epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes (*Novicrit*)
- 9588P **EPOETIN LAMBDA**, epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes (*Novicrit*)
- 9590R **EPOETIN LAMBDA**, epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes (*Novicrit*)
- 9593X **EPOETIN LAMBDA**, epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes (*Novicrit*)
- 9595B **EPOETIN LAMBDA**, epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes (*Novicrit*)

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## Alterations

### Alteration – Note

9621J	<b>ABATACEPT</b> , abatacept 250 mg injection, 1 vial ( <i>Orencia</i> )
6397Q	<b>INFLIXIMAB</b> , infliximab 100 mg injection, 1 vial ( <i>Inflixtra, Remicade, Renflexis</i> )
6448J	<b>INFLIXIMAB</b> , infliximab 100 mg injection, 1 vial ( <i>Inflixtra, Remicade, Renflexis</i> )
6496X	<b>INFLIXIMAB</b> , infliximab 100 mg injection, 1 vial ( <i>Inflixtra, Remicade, Renflexis</i> )
9617E	<b>INFLIXIMAB</b> , infliximab 100 mg injection, 1 vial ( <i>Inflixtra, Remicade, Renflexis</i> )
9611W	<b>RITUXIMAB</b> , rituximab 500 mg/50 mL injection, 50 mL vial ( <i>Mabthera</i> )
9671B	<b>TOCILIZUMAB</b> , tocilizumab 80 mg/4 mL injection, 4 mL vial ( <i>Actemra</i> )
9672C	<b>TOCILIZUMAB</b> , tocilizumab 200 mg/10 mL injection, 10 mL vial ( <i>Actemra</i> )
9673D	<b>TOCILIZUMAB</b> , tocilizumab 400 mg/20 mL injection, 20 mL vial ( <i>Actemra</i> )

### Alteration – Restriction

The following items have additions, deletions or alterations to restrictions.

9685R	<b>EPOETIN LAMBDA</b> , epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes ( <i>Novicrit</i> )
9686T	<b>EPOETIN LAMBDA</b> , epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes ( <i>Novicrit</i> )
9687W	<b>EPOETIN LAMBDA</b> , epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes ( <i>Novicrit</i> )
9688X	<b>EPOETIN LAMBDA</b> , epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes ( <i>Novicrit</i> )
9588P	<b>EPOETIN LAMBDA</b> , epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes ( <i>Novicrit</i> )
9590R	<b>EPOETIN LAMBDA</b> , epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes ( <i>Novicrit</i> )
9593X	<b>EPOETIN LAMBDA</b> , epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes ( <i>Novicrit</i> )
9595B	<b>EPOETIN LAMBDA</b> , epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes ( <i>Novicrit</i> )

## Highly Specialised Drugs Program (Public Hospital)

### Deletions

#### Deletion – Item

10227G	<b>APOMORPHINE</b> , apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules ( <i>Apomine</i> )
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#### Deletion – Brand

5618Q	<i>APO-BOSENTAN, GX</i> – <b>BOSENTAN</b> , bosentan 62.5 mg tablet, 60
5619R	<i>APO-BOSENTAN, GX</i> – <b>BOSENTAN</b> , bosentan 125 mg tablet, 60

#### Deletion – Note

9668W	<b>EPOETIN LAMBDA</b> , epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes ( <i>Novicrit</i> )
9669X	<b>EPOETIN LAMBDA</b> , epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes ( <i>Novicrit</i> )
9670Y	<b>EPOETIN LAMBDA</b> , epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes ( <i>Novicrit</i> )
9587N	<b>EPOETIN LAMBDA</b> , epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes ( <i>Novicrit</i> )
9589Q	<b>EPOETIN LAMBDA</b> , epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes ( <i>Novicrit</i> )
9591T	<b>EPOETIN LAMBDA</b> , epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes ( <i>Novicrit</i> )
9594Y	<b>EPOETIN LAMBDA</b> , epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes ( <i>Novicrit</i> )
9596C	<b>EPOETIN LAMBDA</b> , epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes ( <i>Novicrit</i> )

## Alterations

### Alteration – Note

5605B	<b>ABATACEPT</b> , abatacept 250 mg injection, 1 vial ( <i>Orencia</i> )
5753T	<b>INFLIXIMAB</b> , infliximab 100 mg injection, 1 vial ( <i>Inflixtra, Remicade, Renflexis</i> )
5756Y	<b>INFLIXIMAB</b> , infliximab 100 mg injection, 1 vial ( <i>Inflixtra, Remicade, Renflexis</i> )
5757B	<b>INFLIXIMAB</b> , infliximab 100 mg injection, 1 vial ( <i>Inflixtra, Remicade, Renflexis</i> )
5758C	<b>INFLIXIMAB</b> , infliximab 100 mg injection, 1 vial ( <i>Inflixtra, Remicade, Renflexis</i> )

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- 9544H **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Mabthera*)  
9657G **TOCILIZUMAB**, tocilizumab 80 mg/4 mL injection, 4 mL vial (*Actemra*)  
9658H **TOCILIZUMAB**, tocilizumab 200 mg/10 mL injection, 10 mL vial (*Actemra*)  
9659J **TOCILIZUMAB**, tocilizumab 400 mg/20 mL injection, 20 mL vial (*Actemra*)

#### **Alteration – Restriction**

The following items have additions, deletions or alterations to restrictions.

- 9668W **EPOETIN LAMBDA**, epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes (*Novicrit*)  
9669X **EPOETIN LAMBDA**, epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes (*Novicrit*)  
9670Y **EPOETIN LAMBDA**, epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes (*Novicrit*)  
9587N **EPOETIN LAMBDA**, epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes (*Novicrit*)  
9589Q **EPOETIN LAMBDA**, epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes (*Novicrit*)  
9591T **EPOETIN LAMBDA**, epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes (*Novicrit*)  
9594Y **EPOETIN LAMBDA**, epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes (*Novicrit*)  
9596C **EPOETIN LAMBDA**, epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes (*Novicrit*)

## **Highly Specialised Drugs Program (Community Access)**

### **Additions**

#### **Addition – Item**

- 11214F **DARUNAVIR**, darunavir 600 mg tablet, 60 (*Darunavir Mylan*)  
11203P **DARUNAVIR**, darunavir 800 mg tablet, 30 (*Darunavir Mylan*)

#### **Addition – Equivalence Indicator**

- 10329P *Prezista, JC* – **DARUNAVIR**, darunavir 600 mg tablet, 60  
10367P *Prezista, JC* – **DARUNAVIR**, darunavir 800 mg tablet, 30

#### **Addition – Note**

- 10329P **DARUNAVIR**, darunavir 600 mg tablet, 60 (*Prezista*)  
10367P **DARUNAVIR**, darunavir 800 mg tablet, 30 (*Prezista*)

### **Deletions**

#### **Deletion – Item**

- 10352W **FOSCARNET**, FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6 (*Foscavir*)

## **Growth Hormone Program**

### **Advance Notices**

**1 February 2018**

#### **Deletion – Brand**

- 10441M *Omnitrope, SZ* – **SOMATROPIN**, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge  
10481P *Omnitrope, SZ* – **SOMATROPIN**, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge  
6311E *Omnitrope, SZ* – **SOMATROPIN**, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

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## Repatriation Pharmaceutical Benefits

### Advance Notices

**1 March 2018**

#### **Deletion – Brand**

2220W *Actonel EC Combi, UA* – **RISEDRONATE (&) CALCIUM CARBONATE**, RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

**1 May 2018**

#### **Deletion – Brand**

2254P *Actonel EC Combi D, UA* – **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**, RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1



# About the Schedule

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

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

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

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

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

## Symbols and Abbreviations Used in the Schedule

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

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## Restricted Benefits

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

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

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

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

# Guidelines and General Statements

## General Statement for Lipid-Lowering Drugs

Use the following criteria to determine patient eligibility for subsidisation under the PBS for lipid modifying agents.

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use is in accordance with the registered indications which differ between agents in this class - refer to the current Product Information for details. Note also that patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but is outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility.

Patients in very high risk categories (see below) may commence drug therapy with statins or fibrates immediately (ie simultaneously with an appropriate diet). For all other patients, dietary therapy should be trialled prior to initiation of drug therapy.

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

Patients identified as being in one of the following very high risk categories may commence drug therapy with statins or fibrates at any cholesterol level:

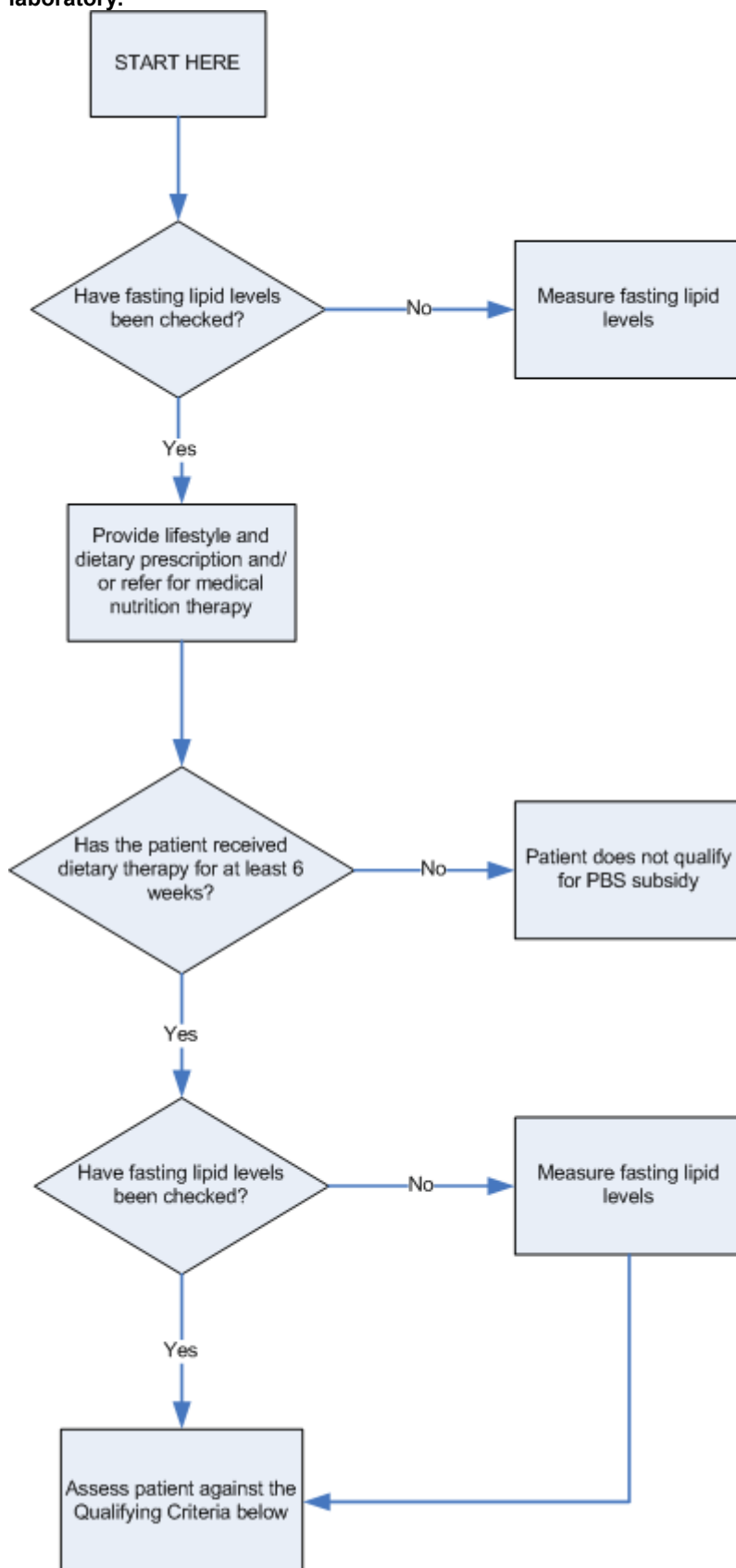
- coronary heart disease which has become symptomatic
- cerebrovascular disease which has become symptomatic
- peripheral vascular disease which has become symptomatic
- diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of >20mcg/min or urinary albumin to creatinine ratio of > 2.5 for males, > 3.5 for females)
- diabetes mellitus in Aboriginal or Torres Strait Islander patients
- diabetes mellitus in patients aged 60 years or more
- family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives
- family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives

### POST-DIETARY QUALIFYING CRITERIA

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

PATIENT CATEGORY	LIPID LEVELS FOR PBS SUBSIDY
Patients with diabetes mellitus not otherwise included	total cholesterol > 5.5 mmol/L
Aboriginal or Torres Strait Islander patients Patients with hypertension	total cholesterol > 6.5 mmol/L <b>or</b> total cholesterol > 5.5 mmol/L <b>and</b> HDL cholesterol < 1 mmol/L
Patients with HDL cholesterol < 1 mmol/L	total cholesterol > 6.5 mmol/L
Patients with familial hypercholesterolaemia identified by: <ul style="list-style-type: none"> <li>• DNA mutation; or</li> <li>• tendon xanthomas in the patient or their first or second degree relative</li> </ul> Patients with: <ul style="list-style-type: none"> <li>• family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or</li> <li>• family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives</li> </ul>	If aged 18 years or less at treatment initiation: LDL cholesterol > 4 mmol/L  If aged more than 18 years at treatment initiation: LDL cholesterol > 5 mmol/L <b>or</b> total cholesterol > 6.5 mmol/L <b>or</b> total cholesterol > 5.5 mmol/L <b>and</b> HDL cholesterol < 1 mmol/L
Patients not eligible under the above: <ul style="list-style-type: none"> <li>• men aged 35 to 75 years</li> <li>• post-menopausal women aged up to 75 years</li> </ul>	total cholesterol > 7.5 mmol/L <b>or</b> triglyceride > 4 mmol/L
Patients not otherwise included	total cholesterol > 9 mmol/L <b>or</b> triglyceride > 8 mmol/L

If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.



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

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

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

### Population criteria:

Patient must be aged 18 years or older.

### Treatment criteria:

Must be treated by a medical practitioner or an authorised nurse practitioner<sup>1</sup> experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.

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

- the hepatitis C virus genotype; and
- the patient's cirrhotic status (non-cirrhotic or cirrhotic)

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

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

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

### HEPATITIS C - NON-CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
Genotype 1	LEDIPASVIR + SOFOSBUVIR [8 or 12 weeks] <sup>2</sup> OR DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR [12 weeks] <sup>3</sup> OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 weeks] <sup>4</sup> OR GRAZOPREVIR + ELBASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]	LEDIPASVIR + SOFOSBUVIR [12 weeks] OR DACLATASVIR and SOFOSBUVIR [12 or 24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR [12 weeks] <sup>3</sup> OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 weeks] <sup>4</sup> OR GRAZOPREVIR + ELBASVIR [12 weeks] OR GRAZOPREVIR + ELBASVIR and RBV [16 weeks] <sup>5</sup> OR SOFOSBUVIR + VELPATASVIR [12 weeks]
Genotype 2	SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]	SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]
Genotype 3	DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]	DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]
Genotype 4	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR GRAZOPREVIR + ELBASVIR and RBV [16 weeks] <sup>5</sup> OR SOFOSBUVIR + VELPATASVIR [12 weeks]
Genotype 5 & 6	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]

#### KEY

PEG-IFN - peginterferon alfa-2a  
RBV - ribavirin

<sup>1</sup> Medicines for the treatment of hepatitis C are listed for prescribing by authorised nurse practitioners under the General Schedule only. Medicines for the treatment of hepatitis C are not listed for prescribing by authorised nurse practitioners under the S100 Highly Specialised Drugs Program.

<sup>2</sup> [LEDIPASVIR + SOFOSBUVIR] for treatment-naïve, non-cirrhotic patients:

- consider treatment for 8 weeks where pre-treatment HCV RNA is less than 6 million IU/mL;
- otherwise treatment for 12 weeks where pre-treatment HCV RNA is 6 million IU/mL or greater.

<sup>3</sup> [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR] for treatment-naïve and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1b HCV.

<sup>4</sup> [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-naïve and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1a HCV.

<sup>5</sup> [GRAZOPREVIR + ELBASVIR and RBV] for treatment-experienced, non-cirrhotic and cirrhotic patients, treatment for 16 weeks in patients with genotype 1a or 4 HCV who have experienced on-treatment virologic failure to prior treatment.

## HEPATITIS C – CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
Genotype 1	LEDIPASVIR + SOFOSBUVIR [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6</sup>	LEDIPASVIR + SOFOSBUVIR [24 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 or 24 weeks] <sup>7</sup> OR GRAZOPREVIR + ELBASVIR [12 weeks] OR GRAZOPREVIR + ELBASVIR and RBV [16 weeks] <sup>5</sup> OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6</sup>
Genotype 2	SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6</sup>	SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6</sup>
Genotype 3	SOFOSBUVIR and RBV [24 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 or 24 weeks] <sup>8</sup> OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6,9</sup>	DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 or 24 weeks] <sup>8</sup> OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6,9</sup>
Genotype 4	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6</sup>	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR GRAZOPREVIR + ELBASVIR and RBV [16 weeks] <sup>5</sup> OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6</sup>
Genotype 5 & 6	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6</sup>	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] <sup>6</sup>

### KEY

PEG-IFN - peginterferon alfa-2a  
RBV – ribavirin

<sup>6</sup> [SOFOSBUVIR + VELPATASVIR] for patients with decompensated cirrhosis:

- use in combination with ribavirin.

<sup>7</sup> [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-experienced, cirrhotic patients:

- consider treatment for 12 weeks in patients with genotype 1a HCV (except prior null responders to PEG-IFN and RBV) and genotype 1b HCV; or  
- consider treatment for 24 weeks in patients with genotype 1a HCV who have had a previous null response to PEG-IFN and RBV.

<sup>8</sup> [DACLATASVIR and SOFOSBUVIR and RBV] for cirrhotic patients consider a 24 week regimen of where clinically appropriate.

<sup>9</sup> [SOFOSBUVIR + VELPATASVIR] for patients with genotype 3 infection with compensated cirrhosis:

- consider addition of ribavirin.

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# Pharmaceutical Benefits Schedules

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# Prescriber Bag

### ▪ ADRENALINE

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

3451P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	22.58	Link Medical Products Pty Ltd [LM]

### ▪ ATROPINE SULFATE

ATROPINE Injection 600 micrograms in 1 mL, 10

3453R	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	22.76	Pfizer Australia Pty Ltd [PF]

### ▪ BENZATROPINE

benztropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials

10016E	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	263.28	Benztropine Omega [FK]

OR

benztropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules

3457Y	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	95.01	Cogentin [FK]

### ▪ BENZYL PENICILLIN

benzylpenicillin 600 mg injection, 1 vial

3486L	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	5	*36.25	BenPen [CS]

OR

### ▪ PROCAINE PENICILLIN

procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes

3485K	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	85.18	Cilicaine [QA]

### ▪ BENZYL PENICILLIN

benzylpenicillin 3 g injection, 1 vial

3487M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	19.78	BenPen [CS]

### ▪ CHLORPROMAZINE

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

3455W	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	22.70	Largactil [SW]

OR

### ▪ HALOPERIDOL

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

3456X	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	24.20	Serenace [QA]

### ▪ CLONAZEPAM

clonazepam 2.5 mg/mL oral liquid, 10 mL

3478C	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	±1	14.84	Rivotril [RO]

▪ **DEXAMETHASONE SODIUM PHOSPHATE**

**DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5**

3472R	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	17.21	<sup>a</sup> Dexamethasone Mylan [AF]	<sup>a</sup> Hospira Pty Limited [PF]

OR

▪ **HYDROCORTISONE SODIUM SUCCINATE**

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

3470P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	2	*20.89	Solu-Cortef [PF]

OR

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

3471Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	19.85	Solu-Cortef [PF]

▪ **DIAZEPAM**

**diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules**

3458B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	17.11	Hospira Pty Limited [PF]

▪ **DIPHTHERIA TOXOID + TETANUS TOXOID**

**diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials**

10244E	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	136.39	MassBiologics tetanus and diphtheria toxoids adsorbed [CS]

OR

▪ **DIPHTHERIA TOXOID + TETANUS TOXOID**

**diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes**

3463G	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	2	*130.13	ADT Booster [CS]

▪ **FRUSEMIDE**

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

3466K	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	13.24	<sup>a</sup> Frusemide-Claris [AE] <sup>a</sup> Lasix [SW]	<sup>a</sup> Frusemide Sandoz [SZ]

▪ **GLUCAGON HYDROCHLORIDE**

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

3467L	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	50.97	GlucaGen Hypokit [NO]

▪ **GLYCERYL TRINITRATE**

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

3475X	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	‡1	23.01	Nitrolingual Pumpspray [SW]

▪ **HYOSCINE BUTYLBROMIDE**

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

3473T	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	23.43	<sup>a</sup> Buscopan [VZ]	<sup>a</sup> HYOSCINE BUTYLBROMIDE SXP [XC]

▪ **LIGNOCAINE**

**lignocaine hydrochloride anhydrous 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules**

10209H	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	39.16	Pfizer Australia Pty Ltd [PF]

▪ **METHOXYFLURANE**

**methoxyflurane 999.9 mg/g inhalation solution, 3 mL**

3489P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	43.26	Pentrox [DV]

▪ **METOCLOPRAMIDE**

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

3476Y	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	16.80	Maxolon [IA]

OR

▪ **PROCHLORPERAZINE**

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

3477B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	20.77	Stemetil [SW]

▪ **MIDAZOLAM**

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

10178Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	40.32	Pfizer Australia Pty Ltd [PF]

▪ **MORPHINE**

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

3480E	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	23.92	Hospira Pty Limited [PF]

OR

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

10868B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	23.78	Morphine Juno [JU]

OR

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

10862Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	20.42	Morphine Juno [JU]

OR

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

3479D	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
<b>NP</b>	1	21.82	Hospira Pty Limited [PF]

▪ **NALOXONE**

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

10786Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	*153.87	<sup>a</sup> Naloxone Hydrochloride (DBL) [PF]	<sup>a</sup> Naloxone Juno [JU]

▪ **OXYTOCIN**

**oxytocin 10 units/mL injection, 5 x 1 mL ampoules**

10251M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	61.09	Oxytocin Sandoz [SZ]

▪ **PHYTOMENADIONE**

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

10213M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	24.58	Konaktion MM [RO]

▪ **PROMETHAZINE**

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

3488N	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	2	*38.67	Hospira Pty Limited [PF]

▪ **SALBUTAMOL**

**salbutamol 100 microgram/actuation pressurised inhalation, 200 actuations**

3495Y	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	‡1	14.80	<sup>a</sup> Asmol CFC-free [AL]
		16.07	<sup>a</sup> Ventolin CFC-free [GK]

OR

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

3496B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	15.09	<sup>a</sup> APO-Salbutamol [TX]	<sup>a</sup> Butamol 2.5 [QA]
			<sup>a</sup> Salbutamol Actavis [EA]	<sup>a</sup> Salbutamol AN [JU]
			<sup>a</sup> Salbutamol Sandoz [SZ]	
		15.34	<sup>a</sup> Asmol 2.5 uni-dose [AF]	

OR

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

11125M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	‡1	14.10	Ventolin Nebules [GK]

▪ **SALBUTAMOL**

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

11088N	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	‡1	14.23	Ventolin Nebules [GK]

OR

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

3497C	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	15.30	<sup>a</sup> APO-Salbutamol [TX]	<sup>a</sup> Butamol 5 [QA]
			<sup>a</sup> Salbutamol Actavis [EA]	<sup>a</sup> Salbutamol AN [JU]
			<sup>a</sup> Salbutamol Sandoz [SZ]	
		15.55	<sup>a</sup> Asmol 5 uni-dose [AF]	

▪ **TRAMADOL**

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

3484J	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	13.94	<sup>a</sup> Tramadol ACT [EA]	<sup>a</sup> Tramadol Sandoz [SZ]
			<sup>a</sup> Tramal 100 [CS]	

# General Pharmaceutical Benefits

ALIMENTARY TRACT AND METABOLISM.....	33
STOMATOLOGICAL PREPARATIONS .....	33
STOMATOLOGICAL PREPARATIONS.....	33
DRUGS FOR ACID RELATED DISORDERS.....	33
DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD) .....	33
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS .....	40
BELLADONNA AND DERIVATIVES, PLAIN .....	40
PROPULSIVES.....	40
ANTIEMETICS AND ANTINAUSEANTS.....	40
ANTIEMETICS AND ANTINAUSEANTS .....	40
BILE AND LIVER THERAPY .....	47
BILE THERAPY .....	47
DRUGS FOR CONSTIPATION .....	47
DRUGS FOR CONSTIPATION.....	47
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS.....	51
INTESTINAL ANTIINFECTIVES.....	51
ELECTROLYTES WITH CARBOHYDRATES .....	52
ANTIPROPULSIVES.....	52
INTESTINAL ANTIINFLAMMATORY AGENTS .....	53
DIGESTIVES, INCL. ENZYMES.....	56
DIGESTIVES, INCL. ENZYMES .....	56
DRUGS USED IN DIABETES .....	58
INSULINS AND ANALOGUES.....	58
BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS .....	59
VITAMINS.....	83
VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO .....	83
VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12.....	83
MINERAL SUPPLEMENTS .....	83
CALCIUM .....	83
POTASSIUM .....	84
OTHER MINERAL SUPPLEMENTS .....	84
ANABOLIC AGENTS FOR SYSTEMIC USE .....	84
ANABOLIC STEROIDS.....	84
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS.....	85
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS .....	85

<b>BLOOD AND BLOOD FORMING ORGANS .....</b>	<b>86</b>
ANTITHROMBOTIC AGENTS.....	86
ANTITHROMBOTIC AGENTS .....	86
ANTIHEMORRHAGICS.....	101
ANTIFIBRINOLYTICS.....	101
ANTIANEMIC PREPARATIONS .....	102
IRON PREPARATIONS .....	102
VITAMIN B12 AND FOLIC ACID .....	103
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS .....	104
BLOOD AND RELATED PRODUCTS .....	104
OTHER HEMATOLOGICAL AGENTS .....	104
OTHER HEMATOLOGICAL AGENTS .....	104
<b>CARDIOVASCULAR SYSTEM.....</b>	<b>104</b>
CARDIAC THERAPY.....	104
CARDIAC GLYCOSIDES.....	104
ANTIARRHYTHMICS, CLASS I AND III .....	105
CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES .....	106
VASODILATORS USED IN CARDIAC DISEASES .....	107
OTHER CARDIAC PREPARATIONS .....	109
ANTIHYPERTENSIVES .....	109
ANTIADRENERGIC AGENTS, CENTRALLY ACTING .....	109
ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING .....	110
ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON.....	110
DIURETICS .....	110
LOW-CEILING DIURETICS, THIAZIDES .....	110
LOW-CEILING DIURETICS, EXCL. THIAZIDES .....	110
HIGH-CEILING DIURETICS .....	111
POTASSIUM-SPARING AGENTS.....	112
DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION.....	112
PERIPHERAL VASODILATORS .....	113
PERIPHERAL VASODILATORS .....	113
BETA BLOCKING AGENTS .....	113
BETA BLOCKING AGENTS .....	113
CALCIUM CHANNEL BLOCKERS.....	117
SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS .....	117
SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS.....	118
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM.....	119
ACE INHIBITORS, PLAIN.....	119
ACE INHIBITORS, COMBINATIONS .....	123
ANGIOTENSIN II ANTAGONISTS, PLAIN .....	126
ANGIOTENSIN II ANTAGONISTS, COMBINATIONS.....	129
LIPID MODIFYING AGENTS.....	135
LIPID MODIFYING AGENTS, PLAIN.....	135
LIPID MODIFYING AGENTS, COMBINATIONS .....	150
<b>DERMATOLOGICALS .....</b>	<b>166</b>
ANTIFUNGALS FOR DERMATOLOGICAL USE .....	166
ANTIFUNGALS FOR TOPICAL USE.....	166

ANTIFUNGALS FOR SYSTEMIC USE.....	167
ANTIPSORIATICS.....	168
ANTIPSORIATICS FOR TOPICAL USE.....	168
ANTIPSORIATICS FOR SYSTEMIC USE.....	169
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE.....	169
CHEMOTHERAPEUTICS FOR TOPICAL USE.....	169
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS.....	170
CORTICOSTEROIDS, PLAIN.....	170
ANTI-ACNE PREPARATIONS.....	179
ANTI-ACNE PREPARATIONS FOR TOPICAL USE.....	179
ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE.....	180
OTHER DERMATOLOGICAL PREPARATIONS.....	180
OTHER DERMATOLOGICAL PREPARATIONS.....	180
<hr/>	
GENITO URINARY SYSTEM AND SEX HORMONES.....	181
OTHER GYNECOLOGICALS.....	181
CONTRACEPTIVES FOR TOPICAL USE.....	181
OTHER GYNECOLOGICALS.....	182
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM.....	183
HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE.....	183
ANDROGENS.....	185
ESTROGENS.....	188
PROGESTOGENS.....	189
PROGESTOGENS AND ESTROGENS IN COMBINATION.....	190
GONADOTROPINS AND OTHER OVULATION STIMULANTS.....	191
ANTIANDROGENS.....	193
OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM.....	193
UROLOGICALS.....	194
UROLOGICALS.....	194
DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY.....	195
<hr/>	
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	196
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES.....	196
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES.....	196
POSTERIOR PITUITARY LOBE HORMONES.....	196
HYPOTHALAMIC HORMONES.....	198
CORTICOSTEROIDS FOR SYSTEMIC USE.....	198
CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN.....	198
THYROID THERAPY.....	202
THYROID PREPARATIONS.....	202
ANTITHYROID PREPARATIONS.....	203
PANCREATIC HORMONES.....	203
GLYCOGENOLYTIC HORMONES.....	203
CALCIUM HOMEOSTASIS.....	203
PARATHYROID HORMONES AND ANALOGUES.....	203
ANTI-PARATHYROID AGENTS.....	204
<hr/>	
ANTIINFECTIVES FOR SYSTEMIC USE.....	204
ANTIBACTERIALS FOR SYSTEMIC USE.....	204
TETRACYCLINES.....	204
BETA-LACTAM ANTIBACTERIALS, PENICILLINS.....	207

OTHER BETA-LACTAM ANTIBACTERIALS .....	214
SULFONAMIDES AND TRIMETHOPRIM .....	219
MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS .....	220
AMINOGLYCOSIDE ANTIBACTERIALS .....	224
QUINOLONE ANTIBACTERIALS .....	225
OTHER ANTIBACTERIALS .....	227
ANTIMYCOTICS FOR SYSTEMIC USE .....	230
ANTIMYCOTICS FOR SYSTEMIC USE .....	230
ANTIMYCOBACTERIALS .....	235
DRUGS FOR TREATMENT OF TUBERCULOSIS .....	235
DRUGS FOR TREATMENT OF LEPRA .....	235
ANTIVIRALS FOR SYSTEMIC USE .....	236
DIRECT ACTING ANTIVIRALS .....	236
VACCINES .....	245
BACTERIAL VACCINES .....	245
<hr/>	
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	246
ANTINEOPLASTIC AGENTS .....	246
ALKYLATING AGENTS .....	246
ANTIMETABOLITES .....	248
PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS .....	249
CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES .....	249
OTHER ANTINEOPLASTIC AGENTS .....	250
ENDOCRINE THERAPY .....	302
HORMONES AND RELATED AGENTS .....	302
HORMONE ANTAGONISTS AND RELATED AGENTS .....	305
IMMUNOSTIMULANTS .....	310
IMMUNOSTIMULANTS .....	310
IMMUNOSUPPRESSANTS .....	314
IMMUNOSUPPRESSANTS .....	314
<hr/>	
MUSCULO-SKELETAL SYSTEM .....	564
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS .....	564
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON- STERIODS .....	564
SPECIFIC ANTIRHEUMATIC AGENTS .....	571
MUSCLE RELAXANTS .....	572
MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS .....	572
MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS .....	572
ANTIGOUT PREPARATIONS .....	572
ANTIGOUT PREPARATIONS .....	572
DRUGS FOR TREATMENT OF BONE DISEASES .....	573
DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION .....	573
<hr/>	
NERVOUS SYSTEM .....	583
ANALGESICS .....	583
OPIOIDS .....	583
OTHER ANALGESICS AND ANTIPYRETICS .....	599
ANTIMIGRAINE PREPARATIONS .....	601
ANTIEPILEPTICS .....	604
ANTIEPILEPTICS .....	604

ANTI-PARKINSON DRUGS .....	615
ANTICHOLINERGIC AGENTS .....	615
DOPAMINERGIC AGENTS .....	616
PSYCHOLEPTICS.....	622
ANTIPSYCHOTICS.....	622
ANXIOLYTICS .....	637
HYPNOTICS AND SEDATIVES .....	640
PSYCHOANALEPTICS .....	642
ANTIDEPRESSANTS .....	642
PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS .....	651
ANTI-DEMENTIA DRUGS .....	656
OTHER NERVOUS SYSTEM DRUGS.....	663
PARASYMPATHOMIMETICS.....	663
DRUGS USED IN ADDICTIVE DISORDERS .....	663
OTHER NERVOUS SYSTEM DRUGS .....	667
<hr/>	
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS.....	668
ANTIPROTOZOALS .....	668
AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES .....	668
ANTIMALARIALS.....	669
ANTHELMINTICS.....	670
ANTITREMATODALS.....	670
ANTINEMATODAL AGENTS.....	670
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS .....	671
ECTOPARASITICIDES, INCL. SCABICIDES.....	671
<hr/>	
RESPIRATORY SYSTEM.....	671
NASAL PREPARATIONS.....	671
DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE .....	671
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES .....	672
ADRENERGICS, INHALANTS.....	672
OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS .....	678
ADRENERGICS FOR SYSTEMIC USE .....	681
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES .....	682
COUGH AND COLD PREPARATIONS.....	684
COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS.....	684
ANTI-HISTAMINES FOR SYSTEMIC USE .....	684
ANTI-HISTAMINES FOR SYSTEMIC USE.....	684
<hr/>	
SENSORY ORGANS .....	684
OPHTHALMOLOGICALS.....	684
ANTIINFECTIVES.....	684
ANTIINFLAMMATORY AGENTS.....	686
ANTIGLAUCOMA PREPARATIONS AND MIOTICS.....	689
MYDRIATICS AND CYCLOPLEGICS .....	695
DECONGESTANTS AND ANTIALLERGICS.....	696

---

OCULAR VASCULAR DISORDER AGENTS .....	696
OTHER OPHTHALMOLOGICALS .....	705
OTOLOGICALS .....	713
ANTIINFECTIVES .....	713
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION .....	714
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS .....	714
ANTIINFECTIVES .....	714

---

VARIOUS .....	714
ALLERGENS .....	714
ALLERGENS .....	714
ALL OTHER THERAPEUTIC PRODUCTS .....	715
ALL OTHER THERAPEUTIC PRODUCTS .....	715
DIAGNOSTIC AGENTS .....	718
URINE TESTS .....	718
GENERAL NUTRIENTS .....	719
OTHER NUTRIENTS .....	719

## ALIMENTARY TRACT AND METABOLISM

### STOMATOLOGICAL PREPARATIONS

#### STOMATOLOGICAL PREPARATIONS

*Antiinfectives and antiseptics for local oral treatment*

#### AMPHOTERICIN B

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

2931G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	15.72	16.93	Fungilin [QA]

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

3306B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	15.72	16.93	Fungilin [QA]

*Other agents for local oral treatment*

#### BENZYDAMINE

##### Restricted benefit

Mucositis

##### Clinical criteria:

- The condition must be radiation induced.

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

1121B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	24.18	25.39	Difflam [IA]

#### BENZYDAMINE

##### Restricted benefit

Mucositis

##### Clinical criteria:

- The condition must be radiation induced.

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

5032W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	24.18	25.39	Difflam [IA]

## DRUGS FOR ACID RELATED DISORDERS

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

*H2-receptor antagonists*

#### CIMETIDINE

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

##### cimetidine 400 mg tablet, 60

1158Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.09	21.30	Magicul 400 [AF]

#### FAMOTIDINE

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

##### famotidine 40 mg tablet, 30

2488Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14.94	16.15	<sup>a</sup> Ausfam 40 [RW] <sup>a</sup> Famotidine Sandoz [SZ] <sup>a</sup> Pepzan [ED]	<sup>a</sup> Famotidine AN [EA] <sup>a</sup> GenRx Famotidine [GX]

##### famotidine 20 mg tablet, 60

2487X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14.94	16.15	<sup>a</sup> Ausfam 20 [RW] <sup>a</sup> Famotidine Sandoz [SZ] <sup>a</sup> Pepzan [ED]	<sup>a</sup> Famotidine AN [EA] <sup>a</sup> GenRx Famotidine [GX]

## ■ NIZATIDINE

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

### nizatidine 300 mg capsule, 30

1504E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.53	22.74	<sup>a</sup> Nizac [RF]	<sup>a</sup> Tacidine [AF]
			<sup>B</sup> 6.61	28.14	22.74	<sup>a</sup> Tazac [RW]	

### nizatidine 150 mg capsule, 60

1505F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.53	22.74	<sup>a</sup> Nizac [RF]	<sup>a</sup> Tacidine [AF]
			<sup>B</sup> 6.61	28.14	22.74	<sup>a</sup> Tazac [RW]	

## ■ RANITIDINE

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

### ranitidine 150 mg/10 mL oral liquid, 300 mL

8162N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*26.83	28.04	Zantac Syrup [AS]

### ranitidine 300 mg tablet, 30

1977C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.55	15.76	<sup>a</sup> APO-Ranitidine [TX]	<sup>a</sup> Ausran [RW]
						<sup>a</sup> Chem mart Ranitidine [CH]	<sup>a</sup> Rani 2 [AF]
						<sup>a</sup> Ranitidine GH [GQ]	<sup>a</sup> Ranitidine Sandoz [SZ]
						<sup>a</sup> Terry White Chemists Ranitidine [TW]	
						<sup>B</sup> 1.68	16.23

## ■ RANITIDINE

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

**Note** Pharmaceutical benefits that have the form ranitidine tablet 150 mg (as hydrochloride) and pharmaceutical benefits that have the form ranitidine tablet, effervescent, 150 mg (as hydrochloride) are equivalent for the purposes of substitution.

### ranitidine 150 mg effervescent tablet, 30

1937Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	<sup>B</sup> 1.16	*16.15	16.20	<sup>a</sup> Zantac [AS]

### ranitidine 150 mg tablet, 60

1978D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	5	..	14.55	15.76	<sup>a</sup> APO-Ranitidine [TX]	<sup>a</sup> Ausran [RW]
						<sup>a</sup> Chem mart Ranitidine [CH]	<sup>a</sup> Rani 2 [AF]
						<sup>a</sup> Ranitidine AN [EA]	<sup>a</sup> Ranitidine GH [GQ]
						<sup>a</sup> Ranitidine Sandoz [SZ]	<sup>a</sup> Terry White Chemists Ranitidine [TW]
						<sup>a</sup> Ulcaid [RA]	
						<sup>B</sup> 1.68	16.23

### Proton pump inhibitors

## ■ ESOMEPRAZOLE

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

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

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

### Restricted benefit

Gastro-oesophageal reflux disease

### Clinical criteria:

- The treatment must be for the healing of gastro-oesophageal reflux disease.

### esomeprazole 40 mg capsule, 30

10330Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	27.76	28.97	<sup>a</sup> Esomeprazole ACTAVIS [EA]	<sup>a</sup> Noxicid Caps [AL]

**esomeprazole 40 mg enteric tablet, 30**

8601Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	27.76	28.97	<sup>a</sup> Esomeprazole Apotex [TX] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Sandoz [SZ] <sup>a</sup> Nexium [AP] <sup>a</sup> Pharmacor Esomeprazole [CR]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> Nexazole [RW] <sup>a</sup> Nexole [RF]

**■ ESOMEPRAZOLE**

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

**Note Continuing Therapy Only:**

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

**Authority required**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Authority required**

Scleroderma oesophagus

**esomeprazole 40 mg capsule, 30**

10331R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.76	28.97	<sup>a</sup> Esomeprazole ACTAVIS [EA]	<sup>a</sup> Noxicid Caps [AL]

**esomeprazole 40 mg enteric tablet, 30**

3401B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.76	28.97	<sup>a</sup> Esomeprazole Apotex [TX] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Sandoz [SZ] <sup>a</sup> Nexium [AP] <sup>a</sup> Pharmacor Esomeprazole [CR]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> Nexazole [RW] <sup>a</sup> Nexole [RF]

**■ ESOMEPRAZOLE**

**Note** *Helicobacter pylori* eradication therapy should be considered.

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

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

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

**Restricted benefit**

Gastric ulcer

Treatment Phase: Initial treatment

**esomeprazole 20 mg enteric tablet, 30**

8886Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	20.92	22.13	<sup>a</sup> Esomeprazole Apotex [TX] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Sandoz [SZ] <sup>a</sup> Nexium [AP] <sup>a</sup> Pharmacor Esomeprazole [CR]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> Nexazole [RW] <sup>a</sup> Nexole [RF]

**esomeprazole 20 mg capsule, 30**

10295W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	20.92	22.13	<sup>a</sup> Esomeprazole ACTAVIS [EA]	<sup>a</sup> Noxicid Caps [AL]

**■ ESOMEPRAZOLE**

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

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- The condition must be healed.

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**esomeprazole 20 mg enteric tablet, 30**

8600P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.92	22.13	<sup>a</sup> Esomeprazole Apotex [TX] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Sandoz [SZ] <sup>a</sup> Nexium [AP] <sup>a</sup> Pharmacor Esomeprazole [CR]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> Nexazole [RW] <sup>a</sup> Nexole [RF]

**esomeprazole 20 mg capsule, 30**

10343J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.92	22.13	<sup>a</sup> Esomeprazole ACTAVIS [EA]	<sup>a</sup> Noxicid Caps [AL]

**■ LANSOPRAZOLE****Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

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

9331D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.23	15.44	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>b</sup> 3.98	18.21	15.44	<sup>a</sup> Zoton FasTabs [PF]	

**lansoprazole 15 mg enteric capsule, 30**

8198L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.46	15.67	Zopral [AF]

**■ LANSOPRAZOLE**

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

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

9478W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.72	17.93	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>b</sup> 3.99	20.71	17.93	<sup>a</sup> Zoton FasTabs [PF]	

**lansoprazole 30 mg enteric capsule, 28**

2241Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.72	17.93	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]

**■ LANSOPRAZOLE**

**Note** *Helicobacter pylori* eradication therapy should be considered.

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

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

**Restricted benefit**

Peptic ulcer

Treatment Phase: Initial treatment

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

9477T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	16.72	17.93	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>b</sup> 3.99	20.71	17.93	<sup>a</sup> Zoton FasTabs [PF]	

**lansoprazole 30 mg enteric capsule, 28**

2240X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	16.72	17.93	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]

**■ OMEPRAZOLE****Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Zollinger-Ellison syndrome

**omeprazole 10 mg enteric tablet, 30**

8332M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.71	15.92	Losec Tablets [AP]	

**■ OMEPRAZOLE****Note** *Helicobacter pylori* eradication therapy should be considered.**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Peptic ulcer

Treatment Phase: Initial treatment

**omeprazole 20 mg enteric tablet, 30**

8331L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.52	16.73	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> Meprazol [SZ] <sup>a</sup> Omeprazole generichealth [GQ] <sup>a</sup> Terry White Chemists Omeprazole [TW]	<sup>a</sup> Chem mart Omeprazole [CH] <sup>a</sup> Omeprazole AN [EA] <sup>a</sup> Ozmepr [ZP]

**omeprazole 20 mg enteric tablet, 30**

9109K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.52	16.73	<sup>a</sup> Acimax Tablets [AL] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [ZA]
			<sup>b</sup> 3.06	18.58	16.73	<sup>a</sup> Losec Tablets [AP]	

**omeprazole 20 mg capsule, 30**

1326T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.52	16.73	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]	<sup>a</sup> Maxor [AF] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]

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

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Zollinger-Ellison syndrome

**omeprazole 20 mg enteric tablet, 30**

8333N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.52	16.73	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> Meprazol [SZ] <sup>a</sup> Omeprazole generichealth [GQ] <sup>a</sup> Terry White Chemists Omeprazole [TW]	<sup>a</sup> Chem mart Omeprazole [CH] <sup>a</sup> Omeprazole AN [EA] <sup>a</sup> Ozmepr [ZP]

**omeprazole 20 mg enteric tablet, 30**

9110L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.52	16.73	<sup>a</sup> Acimax Tablets [AL] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [ZA]
			<sup>B</sup> 3.06	18.58	16.73	<sup>a</sup> Losec Tablets [AP]	

**omeprazole 20 mg capsule, 30**

1327W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.52	16.73	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]	<sup>a</sup> Maxor [AF] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]

**■ PANTOPRAZOLE**

**Note** *Helicobacter pylori* eradication therapy should be considered.

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

**Restricted benefit**

Peptic ulcer

Treatment Phase: Initial treatment

 **pantoprazole 40 mg enteric tablet, 30**

8007K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	13.64	14.85	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Panthron [ER] <sup>a</sup> Pantofast 40 [RZ] <sup>a</sup> Pantoprazole AN [EA] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Somac [NQ] <sup>a</sup> Topra 40 [DO]	<sup>a</sup> APOTEX-Pantoprazole [GX] <sup>a</sup> Ozpan [RA] <sup>a</sup> Panto [TK] <sup>a</sup> Pantoprazole Actavis [ED] <sup>a</sup> Pantoprazole GH [GQ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

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

9423Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	32.21	33.42	Somac [NQ]	

**■ PANTOPRAZOLE****Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Zollinger-Ellison syndrome

 **pantoprazole 40 mg enteric tablet, 30**

8008L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.64	14.85	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Panthron [ER] <sup>a</sup> Pantofast 40 [RZ] <sup>a</sup> Pantoprazole AN [EA] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Somac [NQ] <sup>a</sup> Topra 40 [DO]	<sup>a</sup> APOTEX-Pantoprazole [GX] <sup>a</sup> Ozpan [RA] <sup>a</sup> Panto [TK] <sup>a</sup> Pantoprazole Actavis [ED] <sup>a</sup> Pantoprazole GH [GQ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

 **pantoprazole 20 mg enteric tablet, 30**

8399C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.34	13.55	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> Ozpan [RA] <sup>a</sup> Panto [TK] <sup>a</sup> Pantoprazole AN [EA] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Somac [NQ]	<sup>a</sup> APOTEX-Pantoprazole [GX] <sup>a</sup> Panthron [ER] <sup>a</sup> Pantofast 20 [RZ] <sup>a</sup> Pantoprazole GH [GQ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

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

9424B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	32.21	33.42	Somac [NQ]	

## ▪ RABEPRAZOLE

### Restricted benefit

Gastro-oesophageal reflux disease

### Restricted benefit

Scleroderma oesophagus

### rabeprazole sodium 20 mg enteric tablet, 30

8508T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14.13	15.34	<sup>a</sup> APO-Rabeprazole [TX] <sup>a</sup> Parbezol [RW] <sup>a</sup> Rabeprazole AN [EA] <sup>a</sup> Rabeprazole generichealth [GQ] <sup>a</sup> Rabeprazole SUN [RN] <sup>a</sup> Terry White Chemists Rabeprazole [TW]	<sup>a</sup> Chem mart Rabeprazole [CH] <sup>a</sup> Parzol 20 [ZP] <sup>a</sup> Rabeprazole-DRLA [RZ] <sup>a</sup> Rabeprazole Sandoz [SZ] <sup>a</sup> Razit 20 [DO] <sup>a</sup> Zabep [AL]
			<sup>b</sup> 3.95	18.08	15.34	<sup>a</sup> Pariet [JC]	

### rabeprazole sodium 10 mg enteric tablet, 28

8507R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14.13	15.34	<sup>a</sup> APO-Rabeprazole [TX] <sup>a</sup> Parzol 10 [ZP] <sup>a</sup> Rabeprazole-DRLA [RZ]  <sup>a</sup> Rabeprazole Sandoz [SZ]	<sup>a</sup> Parbezol [RW] <sup>a</sup> Rabeprazole AN [EA] <sup>a</sup> Rabeprazole generichealth [GQ] <sup>a</sup> Razit 10 [DO]
			<sup>b</sup> 3.95	18.08	15.34	<sup>a</sup> Pariet [JC]	

## ▪ RABEPRAZOLE

**Note** *Helicobacter pylori* eradication therapy should be considered.

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

### Restricted benefit

Peptic ulcer

Treatment Phase: Initial treatment

### rabeprazole sodium 20 mg enteric tablet, 30

8509W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	14.13	15.34	<sup>a</sup> APO-Rabeprazole [TX] <sup>a</sup> Parbezol [RW] <sup>a</sup> Rabeprazole AN [EA] <sup>a</sup> Rabeprazole generichealth [GQ] <sup>a</sup> Rabeprazole SUN [RN] <sup>a</sup> Terry White Chemists Rabeprazole [TW]	<sup>a</sup> Chem mart Rabeprazole [CH] <sup>a</sup> Parzol 20 [ZP] <sup>a</sup> Rabeprazole-DRLA [RZ] <sup>a</sup> Rabeprazole Sandoz [SZ] <sup>a</sup> Razit 20 [DO] <sup>a</sup> Zabep [AL]
			<sup>b</sup> 3.95	18.08	15.34	<sup>a</sup> Pariet [JC]	

*Combinations for eradication of Helicobacter pylori*

## ▪ ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXYCILLIN

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

### Restricted benefit

Eradication of *Helicobacter pylori*

### Clinical criteria:

- The condition must be associated with peptic ulcer disease.

### esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxicillin 500 mg capsule [28 capsules], 1 pack

10759G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	40.67	38.80	<sup>a</sup> ESOMEPRAZOLE SANDOZ Hp7 [SZ]

### esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxicillin 500 mg capsule [28 capsules], 1 pack

8738X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	40.67	38.80	<sup>a</sup> Nexium Hp7 [AP]

*Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)*

## ■ SUCRALFATE

### sucralfate 1 g tablet, 120

2055E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	26.68	27.89	Carafate [AS]

## ■ DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, tertiary amines*

## ■ ATROPINE SULFATE

### ATROPINE Injection 600 micrograms in 1 mL, 10

5022H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	22.76	23.97	Pfizer Australia Pty Ltd [PF]

## ■ ATROPINE SULFATE

#### Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### ATROPINE Injection 600 micrograms in 1 mL, 10

1089H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	22.76	23.97	Pfizer Australia Pty Ltd [PF]

## PROPULSIVES

*Propulsives*

## ■ DOMPERIDONE

### domperidone 10 mg tablet, 25

1347X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	13.13	14.34	Motilium [JC]

## ■ METOCLOPRAMIDE

### metoclopramide hydrochloride 10 mg tablet, 25

1207M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	12.22	13.43	<sup>a</sup> APO-Metoclopramide [TX]	<sup>a</sup> EMEXLON [RW]
						<sup>a</sup> Metoclopramide AN [EA]	<sup>a</sup> Metoclopramide RBX [RA]
						<sup>a</sup> Pramin [AF]	
			<sup>B</sup> 1.91	14.13	13.43	<sup>a</sup> Maxolon [IA]	

### metoclopramide hydrochloride 10 mg tablet, 25

5151D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	12.22	13.43	<sup>a</sup> APO-Metoclopramide [TX]	<sup>a</sup> EMEXLON [RW]
						<sup>a</sup> Metoclopramide AN [EA]	<sup>a</sup> Metoclopramide RBX [RA]
						<sup>a</sup> Pramin [AF]	
			<sup>B</sup> 1.91	14.13	13.43	<sup>a</sup> Maxolon [IA]	

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

1206L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	16.80	18.01	Maxolon [IA]

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

5153F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.80	18.01	Maxolon [IA]

## ■ ANTIEMETICS AND ANTINAUSEANTS

### ANTIEMETICS AND ANTINAUSEANTS

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

## ■ GRANISETRON

#### Restricted benefit

Nausea and vomiting

**Clinical criteria:**

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

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

8729K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	13.15	14.36	<sup>a</sup> Granisetron-AFT [AE] <sup>a</sup> Kytril [IX]	<sup>a</sup> Granisetron Kabi [PK]

**■ GRANISETRON****Authority required (STREAMLINED)****4092**

Nausea and vomiting

**Clinical criteria:**

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

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

8730L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	13.15	14.36	<sup>a</sup> Granisetron-AFT [AE] <sup>a</sup> Kytril [IX]	<sup>a</sup> Granisetron Kabi [PK]

**■ GRANISETRON****Authority required (STREAMLINED)****4102**

Nausea and vomiting

**Clinical criteria:**

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

**granisetron 2 mg tablet, 5**

8873B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	55.66	38.80	Kytril [IX]

**■ GRANISETRON****Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**granisetron 2 mg tablet, 1**

8728J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*28.91	30.12	Kytril [IX]

**■ NETUPITANT + PALONOSETRON**

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

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

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

**Authority required (STREAMLINED)****5991**

Nausea and vomiting

**Clinical criteria:**

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

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)****5994**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

**6937**

Nausea and vomiting

**Clinical criteria:**

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

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

**6879**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

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

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10731T	±1	5	..	115.56	38.80	Akynzeo [MF]

▪ **ONDANSETRON**

**Authority required (STREAMLINED)**

**4102**

Nausea and vomiting

**Clinical criteria:**

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

**ondansetron 4 mg tablet, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1594X	1	1	..	20.26	21.47	<sup>a</sup> APO-Ondansetron [TX] <sup>a</sup> Ondansetron-DRLA [RZ] <sup>a</sup> Onsetron 4 [ZP] <sup>a</sup> Zofran [AS]	<sup>a</sup> Ondansetron AN [EA] <sup>a</sup> Ondansetron SZ [HX] <sup>a</sup> Zilfojim 4 [DO]

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

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8233H	±1	1	..	97.94	38.80	Zofran syrup 50 mL [AS]

**ondansetron 8 mg tablet, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1595Y	1	1	..	25.48	26.69	<sup>a</sup> APO-Ondansetron [TX] <sup>a</sup> Ondansetron-DRLA [RZ] <sup>a</sup> Onsetron 8 [ZP] <sup>a</sup> Zofran [AS]	<sup>a</sup> Ondansetron AN [EA] <sup>a</sup> Ondansetron SZ [HX] <sup>a</sup> Zilfojim 8 [DO]

▪ **ONDANSETRON**

**Authority required (STREAMLINED)**

**4092**

Nausea and vomiting

**Clinical criteria:**

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

**ondansetron 4 mg/2 mL injection, 2 mL ampoule**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1596B	1	..	..	11.43	12.64	<sup>a</sup> Ondansetron Alphapharm [AF] <sup>a</sup> Onsetron [ZP]	

**ondansetron 8 mg/4 mL injection, 4 mL ampoule**

1597C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.64	12.85	<sup>a</sup> Ondansetron Alphapharm [AF]	<sup>a</sup> Onsetron [ZP]

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

Nausea and vomiting

**Clinical criteria:**

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

**ondansetron 4 mg tablet, 4**

8224W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.76	15.97	<sup>a</sup> APO-Ondansetron [TX] <sup>a</sup> Ondansetron-DRLA [RZ] <sup>a</sup> Onsetron 4 [ZP]	<sup>a</sup> Ondansetron AN [EA] <sup>a</sup> Ondansetron SZ [HX] <sup>a</sup> Zofran [AS]

**ondansetron 8 mg tablet, 4**

8225X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.84	18.05	<sup>a</sup> APO-Ondansetron [TX] <sup>a</sup> Ondansetron-DRLA [RZ] <sup>a</sup> Onsetron 8 [ZP]	<sup>a</sup> Ondansetron AN [EA] <sup>a</sup> Ondansetron SZ [HX] <sup>a</sup> Zofran [AS]

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

Nausea and vomiting

**Clinical criteria:**

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

**ondansetron 4 mg/2 mL injection, 2 mL ampoule**

8226Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.43	12.64	<sup>a</sup> Ondansetron Alphapharm [AF]	<sup>a</sup> Onsetron [ZP]

**ondansetron 8 mg/4 mL injection, 4 mL ampoule**

8227B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.64	12.85	<sup>a</sup> Ondansetron Alphapharm [AF]	<sup>a</sup> Onsetron [ZP]

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

Nausea and vomiting

**Clinical criteria:**

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

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

9441X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	97.94	38.80	Zofran syrup 50 mL [AS]

**■ ONDANSETRON**

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

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

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

**ONDANSETRON Tablet (orally disintegrating) 8 mg, 4**

5471Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.84	18.05	<sup>a</sup> Ondansetron AN ODT [EA]	<sup>a</sup> Ondansetron ODT-DRLA [RZ]

<sup>a</sup> Ondansetron ODT GH [GQ] <sup>a</sup> Ondansetron SZ ODT [HX]**ondansetron 8 mg wafer, 4**

8411Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	<sup>B</sup> 2.45	19.29	18.05	<sup>a</sup> Zofran Zydis [AS]

**ondansetron 4 mg wafer, 4**

8410P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	<sup>B</sup> 2.45	17.21	15.97	<sup>a</sup> Zofran Zydis [AS]

**ONDANSETRON Tablet (orally disintegrating) 4 mg, 4**

5470X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	14.76	15.97	<sup>a</sup> Ondansetron AN ODT [EA] <sup>a</sup> Ondansetron ODT GH [GQ]	<sup>a</sup> Ondansetron ODT-DRLA [RZ] <sup>a</sup> Ondansetron SZ ODT [HX]

**■ ONDANSETRON**

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

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

**Authority required (STREAMLINED)****5777**

Nausea and vomiting

**Clinical criteria:**

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

**ondansetron 4 mg wafer, 10**

8412R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	<sup>B</sup> 2.45	22.71	21.47	<sup>a</sup> Zofran Zydis [AS]

**ONDANSETRON Tablet (orally disintegrating) 4 mg, 10**

5472B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	20.26	21.47	<sup>a</sup> Ondansetron AN ODT [EA] <sup>a</sup> Ondansetron ODT GH [GQ] <sup>a</sup> Zilfojim ODT 4 [DO]	<sup>a</sup> Ondansetron ODT-DRLA [RZ] <sup>a</sup> Ondansetron SZ ODT [HX]

**ondansetron 8 mg wafer, 10**

8413T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	<sup>B</sup> 2.45	27.93	26.69	<sup>a</sup> Zofran Zydis [AS]

**ONDANSETRON Tablet (orally disintegrating) 8 mg, 10**

5473C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	25.48	26.69	<sup>a</sup> Ondansetron AN ODT [EA] <sup>a</sup> Ondansetron ODT GH [GQ] <sup>a</sup> Zilfojim ODT 8 [DO]	<sup>a</sup> Ondansetron ODT-DRLA [RZ] <sup>a</sup> Ondansetron SZ ODT [HX]

**■ PALONOSETRON**

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

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

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

5295Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	46.18	38.80	Aloxi [MF]

**■ TROPISETRON****Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

**tropisetron 5 mg/5 mL injection, 5 mL ampoule**

2746M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	16.00	17.21	Tropisetron-AFT [AE]

**Other antiemetics****■ APREPITANT**

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

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

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

**Authority required (STREAMLINED)****4211**

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)****4215**

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)****6444**

Nausea and vomiting

**Clinical criteria:**

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

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

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

**Authority required (STREAMLINED)****6370**

Nausea and vomiting

**Clinical criteria:**

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

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

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

**aprepitant 165 mg capsule, 1**

2518M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	115.56	38.80	Emend [MK]

**■ FOSAPREPITANT**

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

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

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

**Authority required (STREAMLINED)****6886**

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)****6891**

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)****6887**

Nausea and vomiting

**Clinical criteria:**

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

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

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

**Authority required (STREAMLINED)****6852**

Nausea and vomiting

**Clinical criteria:**

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

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

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

**fosaprepitant 150 mg injection, 1 vial**

11107N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	115.56	38.80	Emend IV [MK]

**PROCHLORPERAZINE**

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

**prochlorperazine maleate 5 mg tablet, 25**

5205Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	12.06	13.27	<sup>a</sup> APO-Prochlorperazine [TX]	<sup>a</sup> ProCalm [RW]
						<sup>a</sup> Prochlorperazine AN [EA]	<sup>a</sup> Prochlorperazine GH [GQ]
						<sup>a</sup> Stemizine [AV]	
			<sup>B</sup> 3.00	15.06	13.27	<sup>a</sup> Stemetil [SW]	

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

5206B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	20.77	21.98	Stemetil [SW]

**PROCHLORPERAZINE**

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

**Note** As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

**prochlorperazine maleate 5 mg tablet, 25**

2893G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.06	13.27	<sup>a</sup> APO-Prochlorperazine [TX]	<sup>a</sup> ProCalm [RW]
						<sup>a</sup> Prochlorperazine AN [EA]	<sup>a</sup> Prochlorperazine GH [GQ]
						<sup>a</sup> Stemizine [AV]	
			<sup>b</sup> 3.00	15.06	13.27	<sup>a</sup> Stemetil [SW]	

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

2369Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	20.77	21.98	Stemetil [SW]

**■ PROMETHAZINE****promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules**

3374N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*38.67	38.80	Hospira Pty Limited [PF]

**■ BILE AND LIVER THERAPY****BILE THERAPY***Bile acid preparations***■ URSODEOXYCHOLIC ACID**

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****5757**

Primary biliary cirrhosis

**ursodeoxycholic acid 500 mg tablet, 100**

11180K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	288.57	38.80	Ursofalk [OA]

**ursodeoxycholic acid 250 mg capsule, 100**

8448P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*307.49	38.80	<sup>a</sup> APO-Ursodeoxycholic acid [TX]	<sup>a</sup> Ursodox GH [GQ]
						<sup>a</sup> Ursofalk [OA]	<sup>a</sup> Ursosan [BZ]

**■ DRUGS FOR CONSTIPATION****DRUGS FOR CONSTIPATION***Contact laxatives***■ BISACODYL****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**bisacodyl 5 mg enteric tablet, 200**

1259G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.08	18.29	Lax-Tab [AE]

▪ **BISACODYL****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Terminal malignant neoplasia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anorectal congenital abnormalities

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Megacolon

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**bisacodyl 10 mg suppository, 12**

1258F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	4	..	*21.43	22.64	Petrus Bisacodyl Suppositories [PP]

**bisacodyl 10 mg suppository, 10**

1260H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*23.71	24.92	<sup>a</sup> Petrus Bisacodyl Suppositories [PP]
			<sup>B</sup> 1.29	*25.00	24.92	<sup>a</sup> Dulcolax [VZ]

**Bulk-forming laxatives**▪ **RHAMNUS FRANGULA + STERCULIA****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

1104D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	27.57	28.78	Normacol Plus [NE]

*Osmotically acting laxatives***MACROGOL-3350**

**Note** Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

3416T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	18.66	19.87	<sup>a</sup> OsmoLax [KY]

**macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets**

2373X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	18.66	19.87	<sup>a</sup> Herron ClearLax [ON]

**MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**

- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets**

8612G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	18.66	19.87	<sup>a</sup> APO-MACROGOL plus ELECTROLYTES [TX] <sup>a</sup> LaxaCon [EA] <sup>a</sup> Macrovic [RF] <sup>a</sup> Movicol [NE]	<sup>a</sup> Chemists' Own Macrogol with Electrolytes [RW] <sup>a</sup> lax-sachets [AE] <sup>a</sup> Molaxole [HM]

**macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL**

10126Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*21.17	22.38	Movicol Liquid [NE]

**Enemas****▪ BISACODYL****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**bisacodyl 10 mg/5 mL enema, 25 x 5 mL**

1263L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	38.50	38.80	Bisalax [AS]

**▪ SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL

2091C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*29.35	30.56	Micolette [AE]

## ■ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

### INTESTINAL ANTIINFECTIVES

#### Antibiotics

#### ■ NYSTATIN

##### nystatin 500 000 units capsule, 50

1699K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	20.64	21.85	Nilstat [QA]

##### nystatin 500 000 units capsule, 50

3345C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	20.64	21.85	Nilstat [QA]

##### nystatin 500 000 units tablet, 50

1696G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	20.64	21.85	Nilstat [QA]

##### nystatin 500 000 units tablet, 50

3342X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	20.64	21.85	Nilstat [QA]

#### ■ RIFAXIMIN

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

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

**Authority required**

Prevention of hepatic encephalopathy

**Treatment criteria:**

- Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

**Clinical criteria:**

- The treatment must be in combination with lactulose, if lactulose is tolerated, **AND**
- Patient must have had prior episodes of hepatic encephalopathy.

##### rifaximin 550 mg tablet, 56

10001J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	490.78	38.80	Xifaxan [NE]

#### ■ VANCOMYCIN

**Note** Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

**Authority required**

Antibiotic associated pseudomembranous colitis

**Clinical criteria:**

- The condition must be due to **Clostridium difficile**, AND
- The condition must be unresponsive to metronidazole.

**Authority required**

Antibiotic associated pseudomembranous colitis

**Clinical criteria:**

- The condition must be due to **Clostridium difficile**, AND
- Patient must have an intolerance to metronidazole.

**vancomycin 125 mg capsule, 20**

3113W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*219.91	38.80	Vancocin [AS]

**vancomycin 250 mg capsule, 20**

3114X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*434.95	38.80	Vancocin [AS]

**ELECTROLYTES WITH CARBOHYDRATES***Oral rehydration salt formulations***▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID****Authority required**

Rehydration in intestinal failure

**sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

11049M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	30	..	..	*155.35	38.80	<sup>a</sup> Repalyte New Formulation [SW]	<sup>a</sup> restore O.R.S. [EA]

**▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID****Note** Each sachet contains sodium chloride 470 mg, potassium chloride 300 mg, sodium acid citrate 530 mg and glucose 3.56 g.**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

3196F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	15.90	17.11	<sup>a</sup> O.R.S. [AS]	<sup>a</sup> Repalyte New Formulation [SW]
						<sup>a</sup> restore O.R.S. [EA]	

**ANTIPROPULSIVES***Antipropulsives***▪ DIPHENOXYLATE + ATROPINE SULFATE****diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20**

2501P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	12.87	14.08	<sup>a</sup> Lofenoxal [IA]
			<sup>B</sup> 1.51	14.38	14.08	<sup>a</sup> Lomotil [IV]

**▪ LOPERAMIDE****Authority required (STREAMLINED)****6364**

Diarrhoea

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**loperamide hydrochloride 2 mg capsule, 12**

1571Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	12.58	13.79	<sup>a</sup> Gastrex [CR]
			<sup>B</sup> 0.65	13.23	13.79	<sup>a</sup> Imodium [JT]

**▪ LOPERAMIDE****Authority required**

Diarrhoea

**loperamide hydrochloride 2 mg capsule, 12**

10889D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	..	..	*18.55	19.76	<sup>a</sup> Gastrex [CR]
			<sup>b</sup> 3.25	*21.80	19.76	<sup>a</sup> Imodium [JT]

**INTESTINAL ANTIINFLAMMATORY AGENTS***Corticosteroids acting locally***BUDESONIDE****Note Continuing Therapy Only:**

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

**budesonide 2 mg/application enema, 2 x 14 applications**

10034D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	188.64	38.80	Budenofalk [OA]

**HYDROCORTISONE ACETATE****Note Continuing Therapy Only:**

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

**Restricted benefit**

Proctitis

**Restricted benefit**

Ulcerative colitis

**hydrocortisone acetate 10% enema, 21.1 g**

1502C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*40.67	38.80	Colifoam [HM]

**PREDNISOLONE SODIUM PHOSPHATE****Note Continuing Therapy Only:**

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

**prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL**

1920C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	3	..	*198.27	38.80	Predsol [QA]

**PREDNISOLONE SODIUM PHOSPHATE****Note Continuing Therapy Only:**

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

**Restricted benefit**

Proctitis

**Restricted benefit**

Ulcerative colitis

**prednisolone (as sodium phosphate) 5 mg suppository, 10**

2554K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*41.86	38.80	Predsol [QA]

*Aminosalicylic acid and similar agents***BALSALAZIDE**

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****4824**

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**balsalazide sodium 750 mg capsule, 180**

8845M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	113.36	38.80	Colazide [PK]

**▪ MESALAZINE**

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****4824**

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**mesalazine 1.5 g granules, 60 sachets**

9206M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	221.60	38.80	Salofalk [OA]

**mesalazine 800 mg enteric tablet, 90**

11210B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*344.51	38.80	Asacol [EU]

**mesalazine 500 mg granules, 100 sachets**

8598M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*273.23	38.80	Salofalk [OA]

**mesalazine 4 g modified release granules, 30 sachets**

10254Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	287.85	38.80	Pentasa [FP]

**mesalazine 1 g modified release granules, 100 sachets**

8599N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	255.73	38.80	Salofalk [OA]

**mesalazine 1.2 g modified release tablet, 60**

9353G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*391.35	38.80	Mezavant [ZI]

**mesalazine 3 g granules, 30 sachets**

10257W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	221.60	38.80	Salofalk [OA]

**▪ MESALAZINE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****4873**

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**Authority required (STREAMLINED)****4896**

Crohn disease

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**mesalazine 2 g modified release granules, 60 sachets**

2287J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	287.85	38.80	Pentasa [FP]

**mesalazine 250 mg enteric tablet, 100**

1611T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	86.24	38.80	Mesasal [AS]

**mesalazine 500 mg modified release tablet, 100**

2214M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*273.23	38.80	Pentasa [FP]

**mesalazine 1 g modified release granules, 120 sachets**

2234N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	305.91	38.80	Pentasa [FP]

**mesalazine 500 mg enteric tablet, 100**

8731M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*273.23	38.80	Salofalk [OA]

**mesalazine 1 g modified release tablet, 60**

3413P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*305.91	38.80	Pentasa [FP]

**■ MESALAZINE**

**Note** Not for the treatment of Crohn disease

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

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

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Acute episode of mild to moderate ulcerative proctitis

**mesalazine 1 g suppository, 30**

5461K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	123.34	38.80	Salofalk [OA]

**mesalazine 1 g suppository, 30**

8752P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	123.34	38.80	Pentasa [FP]

**■ MESALAZINE**

**Note** Not for the treatment of Crohn disease

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

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

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4888**

Acute episode of mild to moderate ulcerative colitis

**mesalazine 2 g/60 mL enema, 7 x 60 mL**

8616L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*311.39	38.80	Salofalk [OA]

**mesalazine 4 g/60 mL enema, 7 x 60 mL**

8617M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*419.19	38.80	Salofalk [OA]

**mesalazine 1 g/application enema, 14 applications**

8768L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*311.39	38.80	Salofalk [OA]

**mesalazine 1 g/100 mL enema, 7 x 100 mL**

8753Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*311.39	38.80	Pentasa [FP]

**■ OLSALAZINE**

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****4824**

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**olsalazine sodium 250 mg capsule, 100**

1728Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.58	38.80	Dipentum [IX]

**olsalazine sodium 500 mg tablet, 100**

8086N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	94.75	38.80	Dipentum [IX]

**■ SULFASALAZINE****Note Continuing Therapy Only:**

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

**sulfasalazine 500 mg tablet, 100**

2093E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*50.45	38.80	Salazopyrin [PF]

**SULFASALAZINE Tablet 500 mg (enteric coated), 100**

2096H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*54.43	38.80	<sup>a</sup> Pyralin EN [FZ]
			<sup>B</sup> 4.00	*58.43	38.80	<sup>a</sup> Salazopyrin-EN [PF]

**■ SULFASALAZINE**

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

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

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**sulfasalazine 500 mg tablet, 100**

9208P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*50.45	38.80	Salazopyrin [PF]

**SULFASALAZINE Tablet 500 mg (enteric coated), 100**

9209Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*54.43	38.80	<sup>a</sup> Pyralin EN [FZ]
			<sup>B</sup> 4.00	*58.43	38.80	<sup>a</sup> Salazopyrin-EN [PF]

**■ DIGESTIVES, INCL. ENZYMES****DIGESTIVES, INCL. ENZYMES***Enzyme preparations*

## ■ PANCREATIC EXTRACT

### Note Continuing Therapy Only:

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

### pancreatic extract 25 000 units modified release capsule, 100

8021E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	10	..	*133.15	38.80	Creon 25,000 [GO]

### pancreatic extract 40 000 units modified release capsule, 100

9412J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	10	..	*206.89	38.80	Creon 40,000 [GO]

### pancreatic extract 5000 units/100 mg enteric coated granules, 20 g

5453B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	10	..	*127.99	38.80	Creon Micro [GO]

### pancreatic extract 10 000 units modified release capsule, 100

8020D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	10	..	*164.20	38.80	Creon 10,000 [GO]

## ■ PANCREATIC EXTRACT

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

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

### Restricted benefit

Cystic fibrosis

### Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

### pancreatic extract 25 000 units modified release capsule, 100

9227P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*133.15	38.80	Creon 25,000 [GO]

### pancreatic extract 40 000 units modified release capsule, 100

9413K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*206.89	38.80	Creon 40,000 [GO]

### pancreatic extract 5000 units/100 mg enteric coated granules, 20 g

5454C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	21	..	*127.99	38.80	Creon Micro [GO]

### pancreatic extract 10 000 units modified release capsule, 100

9226N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	21	..	*164.20	38.80	Creon 10,000 [GO]

## ■ PANCRELIPASE

### Note Continuing Therapy Only:

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

### pancrelipase 25 000 units capsule, 100

8366H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	10	..	*124.63	38.80	Panzytrat 25000 [TM]

## ■ PANCRELIPASE

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

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

### Restricted benefit

Cystic fibrosis

### Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**pancrelipase 25 000 units capsule, 100**

9229R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*124.63	38.80	Panzytrat 25000 [TM]

**DRUGS USED IN DIABETES****INSULINS AND ANALOGUES***Insulins and analogues for injection, fast-acting***INSULIN ASPART****insulin aspart 100 units/mL injection, 5 x 3 mL cartridges**

8435Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	5	1	..	*240.60	38.80	NovoRapid FlexPen [NF]	NovoRapid Penfill 3 mL [NO]

**insulin aspart 100 units/mL injection, 1 x 10 mL vial**

8571D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	2	..	*143.15	38.80	NovoRapid [NO]

**INSULIN GLULISINE****insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges**

1921D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	5	1	..	*240.60	38.80	Apidra [AV]	Apidra SoloStar [SW]

**insulin glulisine 100 units/mL injection, 1 x 10 mL vial**

9224L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	2	..	*143.15	38.80	Apidra [SW]

**INSULIN LISPRO****insulin lispro 100 units/mL injection, 1 x 10 mL vial**

8084L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	2	..	*143.15	38.80	Humalog [LY]

**insulin lispro 100 units/mL injection, 5 x 3 mL cartridges**

8212F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	5	1	..	*240.60	38.80	Humalog [LY]	Humalog KwikPen [KP]

**INSULIN NEUTRAL BOVINE****Authority required**

Diabetes mellitus

**Clinical criteria:**

- Patient must be intolerant to human insulin.

**insulin neutral bovine 100 units/mL injection, 1 x 10 mL vial**

1713E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	2	..	*394.25	38.80	Hypurin Neutral [AS]

**INSULIN NEUTRAL HUMAN****insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges**

1762R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	5	1	..	*201.35	38.80	Actrapid Penfill 3 mL [NO]	Humulin R [LY]

**insulin neutral human 100 units/mL injection, 1 x 10 mL vial**

1531N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	5	2	..	*121.10	38.80	Actrapid [NO]	Humulin R [LY]

*Insulins and analogues for injection, intermediate-acting***INSULIN ISOPHANE BOVINE****Authority required**

Diabetes mellitus

**Clinical criteria:**

- Patient must be intolerant to human insulin.

**insulin isophane bovine 100 units/mL injection, 1 x 10 mL vial**

1711C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	5	2	..	*394.25	38.80	Hypurin Isophane [AS]	

**■ INSULIN ISOPHANE HUMAN****insulin isophane human 100 units/mL injection, 1 x 10 mL vial**

1533Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	2	..	*121.10	38.80	Humulin NPH [LY]	Protaphane [NO]

**insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges**

1761Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*201.35	38.80	Humulin NPH [LY] Protaphane Penfill 3 mL [NO]	Protaphane InnoLet [NI]

*Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting***■ INSULIN ASPART + INSULIN ASPART PROTAMINE****insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL syringes**

8609D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*240.60	38.80	NovoMix 30 FlexPen [NF]	NovoMix 30 Penfill 3 mL [NO]

**■ INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN****insulin neutral human 50 units/mL + insulin isophane human 50 units/mL injection, 5 x 3 mL cartridges**

2062M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	5	1	..	*201.35	38.80	Mixtard 50/50 Penfill 3 mL [NO]	

**insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL cartridges**

1763T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*201.35	38.80	Humulin 30/70 [LY] Mixtard 30/70 Penfill 3 mL [NO]	Mixtard 30/70 InnoLet [NI]

**insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 1 x 10 mL vial**

1426C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	5	2	..	*121.10	38.80	Humulin 30/70 [LY]	

**■ INSULIN LISPRO + INSULIN LISPRO PROTAMINE****insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges**

8390N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*240.60	38.80	Humalog Mix25 [LY]	Humalog Mix25 KwikPen [KP]

**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges**

8874C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*240.60	38.80	Humalog Mix50 [LY]	Humalog Mix50 KwikPen [KP]

*Insulins and analogues for injection, long-acting***■ INSULIN DETEMIR****Restricted benefit**

Type 1 diabetes

**insulin detemir 100 units/mL injection, 5 x 3 mL cartridges**

9040T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*385.65	38.80	Levemir FlexPen [NF]	Levemir Penfill [NO]

**■ INSULIN GLARGINE****insulin glargine 100 units/mL injection, 5 x 3 mL cartridges**

9039R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*406.25	38.80	Lantus [SW]	Lantus SoloStar [AV]

**BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS***Biguanides*

## ■ METFORMIN

### metformin hydrochloride 1 g tablet, 90

8607B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.78	16.99	<sup>a</sup> APO-Metformin 1000 [TX]	<sup>a</sup> Chem mart Metformin 1000 [CH]
						<sup>a</sup> Diaformin 1000 [AF]	<sup>a</sup> Formet 1000 [RW]
						<sup>a</sup> Glucobete 1000 [DO]	<sup>a</sup> Metformin AN [EA]
						<sup>a</sup> Metformin-GA [ED]	<sup>a</sup> Metformin generichealth 1000 [GQ]
						<sup>a</sup> Metformin Ranbaxy 1000 [RA]	<sup>a</sup> Metformin Sandoz [SZ]
						<sup>a</sup> Pharmacor Metformin 1000 [CR]	<sup>a</sup> Terry White Chemists Metformin 1000 [TW]
			<sup>B</sup> 4.95	20.73	16.99	<sup>a</sup> Diabex 1000 [AL]	

### metformin hydrochloride 500 mg modified release tablet, 120

9435N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.40	16.61	<sup>a</sup> APO-Metformin XR 500 [TX]	<sup>a</sup> Blooms the Chemist Metformin XR 500 [IB]
						<sup>a</sup> Chem mart Metformin XR 500 [CH]	<sup>a</sup> Diaformin XR [AF]
						<sup>a</sup> Metex XR [RW]	<sup>a</sup> Metformin XR 500 APOTEX [GX]
						<sup>a</sup> Terry White Chemists Metformin XR 500 [TW]	
			<sup>B</sup> 4.95	20.35	16.61	<sup>a</sup> Diabex XR [AL]	

### metformin hydrochloride 1 g modified release tablet, 60

3439B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.40	16.61	<sup>a</sup> APO-Metformin XR 1000 [TX]	<sup>a</sup> Blooms the Chemist Metformin XR 1000 [IB]
						<sup>a</sup> Chem mart Metformin XR 1000 [CH]	<sup>a</sup> Diaformin XR 1000 [AF]
						<sup>a</sup> METEX XR 1000 [RW]	<sup>a</sup> Terry White Chemists Metformin XR 1000 [TW]
			<sup>B</sup> 4.95	20.35	16.61	<sup>a</sup> Diabex XR 1000 [AL]	

### metformin hydrochloride 500 mg tablet, 100

2430X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.78	14.99	<sup>a</sup> APO-Metformin 500 [TX]	<sup>a</sup> Chem mart Metformin [CH]
						<sup>a</sup> Diaformin [AF]	<sup>a</sup> FORMET 500 [RF]
						<sup>a</sup> Formet Aspen 500 [RW]	<sup>a</sup> Glucobete 500 [DO]
						<sup>a</sup> Metformin 500 [CR]	<sup>a</sup> Metformin AN [EA]
						<sup>a</sup> Metformin-GA [ED]	<sup>a</sup> Metformin generichealth [GQ]
						<sup>a</sup> Metformin Ranbaxy [RA]	<sup>a</sup> Metformin Sandoz [SZ]
						<sup>a</sup> Terry White Chemists Metformin [TW]	
			<sup>B</sup> 4.95	18.73	14.99	<sup>a</sup> Diabex [AL]	

### metformin hydrochloride 850 mg tablet, 60

1801T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.78	14.99	<sup>a</sup> APO-Metformin 850 [TX]	<sup>a</sup> Chem mart Metformin [CH]
						<sup>a</sup> Diaformin 850 [AF]	<sup>a</sup> FORMET 850 [RF]
						<sup>a</sup> Formet Aspen 850 [RW]	<sup>a</sup> Glucobete 850 [DO]
						<sup>a</sup> Metformin 850 [CR]	<sup>a</sup> Metformin AN [EA]
						<sup>a</sup> Metformin-GA [ED]	<sup>a</sup> Metformin Sandoz [SZ]
						<sup>a</sup> Terry White Chemists Metformin [TW]	
			<sup>B</sup> 4.95	18.73	14.99	<sup>a</sup> Diabex 850 [AL]	

## Sulfonylureas

## ■ GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### glibenclamide 5 mg tablet, 100

2939Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.41	16.62	Daonil [SW]

## ■ GLICLAZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**gliclazide 30 mg modified release tablet, 100**

8535F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.12	18.33	<sup>a</sup> APO-Gliclazide MR [TX] <sup>a</sup> Glyade MR [AF]	<sup>a</sup> Chem mart Gliclazide MR [CH] <sup>a</sup> Terry White Chemists Gliclazide MR [TW]

**gliclazide 60 mg modified release tablet, 60**

9302N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.33	19.54	<sup>a</sup> ARDIX GLICLAZIDE 60mg MR [RX]	
			<sup>b</sup> 4.95	23.28	19.54	<sup>a</sup> Diamicon 60mg MR [SE]	

**gliclazide 80 mg tablet, 100**

2449X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.95	18.16	<sup>a</sup> Chem mart Gliclazide [CH] <sup>a</sup> Glyade [AF] <sup>a</sup> Terry White Chemists Gliclazide [TW]	<sup>a</sup> GenRx Gliclazide [GX] <sup>a</sup> Nidem [RW]

**GLIMEPIRIDE**

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glimepiride 3 mg tablet, 30**

8533D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.44	14.65	<sup>a</sup> APO-Glimepiride [TX] <sup>a</sup> Diapride 3 [RW] <sup>a</sup> Glimepiride AN [EA]	<sup>a</sup> Aylide 3 [AF] <sup>a</sup> Dimirel [AV] <sup>a</sup> Glimepiride Sandoz [SZ]
			<sup>b</sup> 2.19	15.63	14.65	<sup>a</sup> Amaryl [SW]	

**glimepiride 2 mg tablet, 30**

8451T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.94	14.15	<sup>a</sup> APO-Glimepiride [TX] <sup>a</sup> Diapride 2 [RW] <sup>a</sup> Glimepiride AN [EA]	<sup>a</sup> Aylide 2 [AF] <sup>a</sup> Dimirel [AV] <sup>a</sup> Glimepiride Sandoz [SZ]
			<sup>b</sup> 2.18	15.12	14.15	<sup>a</sup> Amaryl [SW]	

**glimepiride 4 mg tablet, 30**

8452W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.99	15.20	<sup>a</sup> APO-Glimepiride [TX] <sup>a</sup> Diapride 4 [RW] <sup>a</sup> Glimepiride AN [EA]	<sup>a</sup> Aylide 4 [AF] <sup>a</sup> Dimirel [AV] <sup>a</sup> Glimepiride Sandoz [SZ]
			<sup>b</sup> 2.19	16.18	15.20	<sup>a</sup> Amaryl [SW]	

**glimepiride 1 mg tablet, 30**

8450R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.06	13.27	<sup>a</sup> APO-Glimepiride [TX] <sup>a</sup> Diapride 1 [RW] <sup>a</sup> Glimepiride AN [EA]	<sup>a</sup> Aylide 1 [AF] <sup>a</sup> Dimirel [AV] <sup>a</sup> Glimepiride Sandoz [SZ]
			<sup>b</sup> 2.23	14.29	13.27	<sup>a</sup> Amaryl [SW]	

**GLIPIZIDE**

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glipizide 5 mg tablet, 100**

2440K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.91	19.12	<sup>a</sup> Melizide [AF]	
			<sup>b</sup> 8.50	26.41	19.12	<sup>a</sup> Minidiab [PF]	

**Combinations of oral blood glucose lowering drugs****ALOGLIPTIN + METFORMIN**

**Note** This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Authority required (STREAMLINED)****4423**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

**4427**

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.

**alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56**

10035E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	61.68	38.80	Nesina Met 12.5/1000 [TK]

**alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56**

10032B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	61.27	38.80	Nesina Met 12.5/850 [TK]

**alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56**

10033C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	60.27	38.80	Nesina Met 12.5/500 [TK]

**▪ DAPAGLIFLOZIN + METFORMIN**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**5631**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**5739**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**5798**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

**5657**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56**

10510E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	61.18	38.80	Xigduo XR 5/1000 [AP]

**dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28**

10516L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.02	38.80	Xigduo XR 10/500 [AP]

**dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28**

10515K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.78	38.80	Xigduo XR 10/1000 [AP]

### ▪ EMPAGLIFLOZIN + METFORMIN

**Note** A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

#### Authority required (STREAMLINED)

**5953**

Diabetes mellitus type 2

#### Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

#### empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

10639Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	63.25	38.80	Jardiamet 12.5 mg/500 mg [BY]

#### empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

10640B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.76	38.80	Jardiamet 12.5 mg/1000 mg [BY]

#### empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

10649L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.76	38.80	Jardiamet 5 mg/1000 mg [BY]

#### empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

10650M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	63.25	38.80	Jardiamet 5 mg/500 mg [BY]

### ▪ EMPAGLIFLOZIN + METFORMIN

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

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

#### Authority required (STREAMLINED)

**5966**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

#### Authority required (STREAMLINED)

**5798**

Diabetes mellitus type 2

#### Clinical criteria:

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

#### **Authority required (STREAMLINED)**

##### **5657**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; **OR**
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

#### **empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

10633P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	63.25	38.80	Jardiamet 12.5 mg/500 mg [BY]

#### **empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

10677Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	64.76	38.80	Jardiamet 12.5 mg/1000 mg [BY]

#### **empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

10627H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	64.76	38.80	Jardiamet 5 mg/1000 mg [BY]

#### **empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

10626G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	63.25	38.80	Jardiamet 5 mg/500 mg [BY]

#### **■ LINAGLIPTIN + METFORMIN**

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

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

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

#### **Authority required (STREAMLINED)**

**6333**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)****6336**

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.

**Authority required (STREAMLINED)****6344**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)****6443**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
 (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

#### linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

10045Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	62.30	38.80	Trajentamet [BY]

#### linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

10044P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	62.74	38.80	Trajentamet [BY]

#### linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

10038H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.23	38.80	Trajentamet [BY]

### ■ METFORMIN + GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

#### metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90

8811R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.42	19.63	Glucovance 500mg/5mg [AL]

#### metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90

8838E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.72	17.93	Glucovance 250mg/1.25mg [AL]

#### metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90

8810Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.43	18.64	Glucovance 500mg/2.5mg [AL]

### ■ ROSIGLITAZONE + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

#### Authority required

Diabetes mellitus type 2

#### **Clinical criteria:**

- Patient must have a contraindication to a sulfonylurea; OR
- Patient must not have tolerated a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
 (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

#### rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56

9060W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.27	38.80	Avandamet [GK]

#### rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56

9059T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.86	38.80	Avandamet [GK]

**rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56**

9062Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	86.71	38.80	Avandamet [GK]

**rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56**

9061X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	85.30	38.80	Avandamet [GK]

**■ SAXAGLIPTIN + METFORMIN**

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6333**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)****6335**

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin.

**Authority required (STREAMLINED)****6344**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56**

10048W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.29	38.80	Kombiglyze XR 2.5/1000 [AP]

**saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28**

10055F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.13	38.80	Kombiglyze XR 5/500 [AP]

**saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28**

10051B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.88	38.80	Kombiglyze XR 5/1000 [AP]

**■ SITAGLIPTIN + METFORMIN**

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6333**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)****6334**

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.

**Authority required (STREAMLINED)****6344**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

**6443**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28**

10089B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.88	38.80	Janumet XR [MK]

**sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56**

9451K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.29	38.80	Janumet [MK]

**sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56**

9449H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.88	38.80	Janumet [MK]

**sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56**

10090C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.29	38.80	Janumet XR [MK]

**sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56**

9450J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.88	38.80	Janumet [MK]

**■ VILDAGLIPTIN + METFORMIN**

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6333**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

**6357**

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.

**Authority required (STREAMLINED)**

**6344**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

5474D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.43	38.80	Galvumet 50/500 [NV]

**vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60**

5475E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.51	38.80	Galvumet 50/850 [NV]

**vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

5476F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.95	38.80	Galvumet 50/1000 [NV]

*Alpha glucosidase inhibitors*

■ **ACARBOSE**

**acarbose 50 mg tablet, 90**

8188Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.59	31.80	<sup>a</sup> Acarbose Mylan [AF] <sup>a</sup> GLYBOSAY [RW]	<sup>a</sup> Glucobay 50 [BN]

**acarbose 100 mg tablet, 90**

8189B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.71	38.80	<sup>a</sup> Acarbose Mylan [AF] <sup>a</sup> GLYBOSAY [RW]	<sup>a</sup> Glucobay 100 [BN]

*Thiazolidinediones*

## ■ PIOGLITAZONE

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1 or an SGLT2 inhibitor.

### Authority required (STREAMLINED)

#### 4363

Diabetes mellitus type 2

#### Clinical criteria:

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

### Authority required (STREAMLINED)

#### 4388

Diabetes mellitus type 2

#### Clinical criteria:

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

### Authority required (STREAMLINED)

#### 4364

Diabetes mellitus type 2

#### Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

### pioglitazone 30 mg tablet, 28

8695P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.04	24.25	<sup>a</sup> Acpio 30 [RF] <sup>a</sup> Actos [TK] <sup>a</sup> Chem mart Pioglitazone [CH] <sup>a</sup> Pioglitazone Sandoz [SZ] <sup>a</sup> Terry White Chemists Pioglitazone [TW]	<sup>a</sup> Actaze [RW] <sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Pioglitazone AN [EA] <sup>a</sup> Prioten 30 [DO] <sup>a</sup> Vexazone [AF]

### pioglitazone 15 mg tablet, 28

8694N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.85	20.06	<sup>a</sup> Acpio 15 [RF] <sup>a</sup> Actos [TK] <sup>a</sup> Chem mart Pioglitazone [CH] <sup>a</sup> Pioglitazone Sandoz [SZ] <sup>a</sup> Prioten 15 [DO]  <sup>a</sup> Vexazone [AF]	<sup>a</sup> Actaze [RW] <sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Pioglitazone AN [EA] <sup>a</sup> Pizaccord [RA] <sup>a</sup> Terry White Chemists Pioglitazone [TW]

### pioglitazone 45 mg tablet, 28

8696Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.62	27.83	<sup>a</sup> Acpio 45 [RF] <sup>a</sup> Actos [TK] <sup>a</sup> Chem mart Pioglitazone [CH] <sup>a</sup> Pioglitazone Sandoz [SZ] <sup>a</sup> Prioten 45 [DO]  <sup>a</sup> Vexazone [AF]	<sup>a</sup> Actaze [RW] <sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Pioglitazone AN [EA] <sup>a</sup> Pizaccord [RA] <sup>a</sup> Terry White Chemists Pioglitazone [TW]

## Dipeptidyl peptidase 4 (DPP-4) inhibitors

### ■ ALOGLIPTIN

**Note** Alogliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

#### Authority required (STREAMLINED)

4349

Diabetes mellitus type 2

#### Clinical criteria:

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.

### alogliptin 25 mg tablet, 28

2986E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.76	38.80	Nesina [TK]

### alogliptin 12.5 mg tablet, 28

2933J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.76	38.80	Nesina [TK]

**alogliptin 6.25 mg tablet, 28**

2944Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.76	38.80	Nesina [TK]

**■ LINAGLIPTIN**

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6346**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)****6363**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)****6376**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2)

inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

### linagliptin 5 mg tablet, 30

3387G	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.61	38.80	Trajenta [BY]

### ▪ SAXAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Note Continuing Therapy Only:**

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

#### Authority required (STREAMLINED)

##### 6346

Diabetes mellitus type 2

##### Clinical criteria:

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

#### Authority required (STREAMLINED)

##### 6363

Diabetes mellitus type 2

##### Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

### saxagliptin 2.5 mg tablet, 28

10128C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	56.38	38.80	Onglyza [AP]

### saxagliptin 5 mg tablet, 28

8983T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	56.38	38.80	Onglyza [AP]

## ■ SITAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

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

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

#### Authority required (STREAMLINED)

##### **6346**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

#### Authority required (STREAMLINED)

##### **6363**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

#### **Authority required (STREAMLINED)**

**6376**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

#### **sitagliptin 25 mg tablet, 28**

9180E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	56.38	38.80	Januvia [MK]

#### **sitagliptin 100 mg tablet, 28**

9182G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	56.38	38.80	Januvia [MK]

#### **sitagliptin 50 mg tablet, 28**

9181F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	56.38	38.80	Januvia [MK]

### ■ VILDAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

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

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

#### **Authority required (STREAMLINED)**

**6346**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**6363**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**vildagliptin 50 mg tablet, 60**

3415R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.61	38.80	Galvus [NV]

**Glucagon-like peptide-1 (GLP-1) analogues**

▪ **EXENATIDE**

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6519**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

**6505**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**exenatide 2 mg/dose injection: modified release, 4 injection devices**

10888C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	130.91	38.80	Bydureon [AP]

**EXENATIDE**

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or an SGLT2 inhibitor.

**Authority required (STREAMLINED)****5500**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)****5478**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
 (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

**5469**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- The treatment must be in combination with metformin unless contraindicated or not tolerated, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
 (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**exenatide 5 microgram/dose injection, 60 doses**

3423E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	66.00	38.80	Byetta 5 microgram [AP]

**exenatide 10 microgram/dose injection, 60 doses**

3424F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	89.54	38.80	Byetta 10 microgram [AP]

**Sodium-glucose co-transporter 2 (SGLT2) inhibitors**

▪ **DAPAGLIFLOZIN**

**Note Continuing Therapy Only:**

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

**Note** This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**4983**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
  - The treatment must be in combination with a sulfonylurea, **AND**
  - Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
  - Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.
- The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.
- The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
 (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**4991**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

**5629**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**dapagliflozin 10 mg tablet, 28**

10011X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	58.27	38.80	Forxiga [AP]

▪ **EMPAGLIFLOZIN**

**Note Continuing Therapy Only:**

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

**Note** This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**5629**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

#### **Authority required (STREAMLINED)**

##### **4983**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

#### **Authority required (STREAMLINED)**

##### **4991**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**empagliflozin 10 mg tablet, 30**

10206E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.64	38.80	Jardiance [BY]

**empagliflozin 25 mg tablet, 30**

10202Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.64	38.80	Jardiance [BY]

## ■ VITAMINS

### VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

#### *Vitamin D and analogues*

#### ■ CALCITRIOL

##### Authority required (STREAMLINED)

##### **5401**

Hypocalcaemia

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

- The condition must be due to renal disease.

##### Authority required (STREAMLINED)

##### **5255**

Hypoparathyroidism

##### Authority required (STREAMLINED)

##### **5089**

Hypophosphataemic rickets

##### Authority required (STREAMLINED)

##### **5114**

Vitamin D-resistant rickets

##### Authority required (STREAMLINED)

##### **5402**

Established osteoporosis

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

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

2502Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	27.21	28.42	<sup>a</sup> APO-Calcitriol [TX]	<sup>a</sup> Calciprox [ER]
						<sup>a</sup> Calcitriol AN [EA]	<sup>a</sup> Kosteo [RW]
						<sup>a</sup> Sical [AF]	
			<sup>b</sup> 2.29	29.50	28.42	<sup>a</sup> Rocaltrol [RO]	

### VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

#### *Vitamin B1, plain*

#### ■ THIAMINE

##### Authority required (STREAMLINED)

##### **5139**

Thiamine deficiency

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

- The treatment must be for prophylaxis.

##### **Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**thiamine hydrochloride 100 mg tablet, 100**

1070H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	14.98	16.19	Betavit [PP]

## ■ MINERAL SUPPLEMENTS

### CALCIUM

#### *Calcium*

## ■ CALCIUM

### Authority required (STREAMLINED)

**4586**

Hyperphosphataemia

#### Clinical criteria:

- The condition must be associated with chronic renal failure.

### CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

3116B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*29.67	30.88	Cal-500 [PP]

### CALCIUM Tablet 600 mg (as carbonate), 240

3117C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	24.12	25.33	Calci-Tab 600 [AE]

## POTASSIUM

### Potassium

## ■ POTASSIUM CHLORIDE

**Note** For item codes 2642C and 1841X, pharmaceutical benefits that have the form tablet 600 mg (sustained release) are equivalent for the purposes of substitution.

### potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 100

2642C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*19.27	20.48	<sup>a</sup> Duro-K [NM]
			<sup>B</sup> 3.00	*22.27	20.48	<sup>a</sup> Slow-K [NV]

### potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200

1841X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	19.26	20.47	<sup>a</sup> Span-K [AS]

## ■ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

### potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg effervescent tablet, 60

3012M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	20.77	21.98	Chlorvescent [AS]

## OTHER MINERAL SUPPLEMENTS

### Magnesium

## ■ MAGNESIUM ASPARTATE DIHYDRATE

### Authority required (STREAMLINED)

**5506**

Hypomagnesaemia

#### Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

### Authority required (STREAMLINED)

**5466**

Chronic renal disease

#### Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

### magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50

5146W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.11	18.32	MagMin (PBS) [BB]	Mag-Sup [PP]

## ■ ANABOLIC AGENTS FOR SYSTEMIC USE

### ANABOLIC STEROIDS

#### Estren derivatives

## ■ NANDROLONE DECANOATE

**Note** Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.

### Authority required

Osteoporosis

#### Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The treatment must be where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

**Authority required**

Osteoporosis

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The treatment must be where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

**Authority required**

Osteoporosis

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The treatment must be where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

**Authority required**

Patients receiving this drug as a pharmaceutical benefit prior to 1 February 2004

**Authority required**

Patients on long-term treatment with corticosteroids

**nandrolone decanoate 50 mg/mL injection, 1 mL syringe**

1671Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	23.29	24.50	Deca-Durabolin [AS]

■ **OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS**

**OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS**

*Amino acids and derivatives*

■ **BETAINE**

**Authority required**

Homocystinuria

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
  - The condition must be treated by or in consultation with a metabolic physician.
- The name of the specialist must be included in the authority application.

**betaine 1 g/g powder for oral liquid, 180 g**

10119N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	565.87	38.80	Cystadane [EU]

*Various alimentary tract and metabolism products*

■ **SAPROPTERIN**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously been issued with an authority prescription for this drug; OR
- Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

## BLOOD AND BLOOD FORMING ORGANS

### sapropterin dihydrochloride 100 mg soluble tablet, 30

10087X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*5309.53	38.80	Kuvan [IO]

#### ■ SAPROPTERIN

**Note** Patients will be eligible for a maximum of one script as initial therapy to enable their response to treatment with sapropterin to be assessed.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Hyperphenylalaninaemia

Treatment Phase: Initial

#### **Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

### sapropterin dihydrochloride 100 mg soluble tablet, 30

10086W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	..	..	*5309.53	38.80	Kuvan [IO]

## ■ BLOOD AND BLOOD FORMING ORGANS

### ■ ANTITHROMBOTIC AGENTS

#### ANTITHROMBOTIC AGENTS

##### *Vitamin K antagonists*

#### ■ WARFARIN

**Caution** The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

#### warfarin sodium 1 mg tablet, 50

2843P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	16.05	17.26	Coumadin [QA]	Marevan [FM]

#### warfarin sodium 5 mg tablet, 50

2211J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.38	18.59	Coumadin [QA]	Marevan [FM]

#### warfarin sodium 2 mg tablet, 50

2209G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	16.33	17.54	Coumadin [QA]

#### warfarin sodium 3 mg tablet, 50

2844Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	16.27	17.48	Marevan [FM]

##### *Heparin group*

#### ■ DALTEPARIN SODIUM

#### dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes

5445N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	114.10	38.80	Fragmin [PF]

#### dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes

8269F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	84.13	38.80	Fragmin [PF]

**dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8603T NP	2	..	..	*95.99	38.80	Fragmin [PF]

**dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2816F NP	2	..	..	*99.55	38.80	Fragmin [PF]

**dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8271H NP	1	1	..	64.60	38.80	Fragmin [PF]

▪ **DALTEPARIN SODIUM**

**Restricted benefit**

Haemodialysis

**dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1296F NP	2	3	..	*218.03	38.80	Fragmin [PF]

**dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1229Q NP	2	3	..	*157.17	38.80	Fragmin [PF]

**dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8641T NP	2	3	..	*95.99	38.80	Fragmin [PF]

**dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8642W NP	2	3	..	*99.55	38.80	Fragmin [PF]

**dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8643X NP	2	3	..	*118.11	38.80	Fragmin [PF]

▪ **DALTEPARIN SODIUM**

**Note** No applications for increased maximum quantities will be authorised.

**Restricted benefit**

Symptomatic venous thromboembolism

Treatment Phase: Management

**Clinical criteria:**

- Patient must have a solid tumour(s).

**dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8958L NP	3	5	..	*324.64	38.80	Fragmin [PF]

**dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8957K NP	3	5	..	*231.58	38.80	Fragmin [PF]

**DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8959M NP	3	5	..	*388.57	38.80	Fragmin [PF]

**DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8960N NP	3	5	..	*465.34	38.80	Fragmin [PF]

**dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes**

8956J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*171.61	38.80	Fragmin [PF]

▪ **ENOXAPARIN SODIUM**

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

8263X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	83.88	38.80	Clexane [SW]

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

8510X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*99.55	38.80	Clexane [SW]

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

8262W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	74.35	38.80	Clexane [SW]

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

8264Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	99.75	38.80	Clexane [SW]

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

8558K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*95.99	38.80	Clexane [SW]

▪ **ENOXAPARIN SODIUM**

Restricted benefit

Haemodialysis

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

5434B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*156.67	38.80	Clexane [SW]

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

8639Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*99.55	38.80	Clexane [SW]

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

8640R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*137.61	38.80	Clexane [SW]

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

5435C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*188.41	38.80	Clexane [SW]

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

8716R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*95.99	38.80	Clexane [SW]

▪ **HEPARIN SODIUM**

**heparin sodium 5000 units/5 mL injection, 50 x 5 mL ampoules**

1463B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	72.69	38.80	Pfizer Australia Pty Ltd [PF]

**heparin sodium 35 000 units/35 mL injection, 35 mL vial**

1076P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*354.67	38.80	Hospira Pty Limited [PF]

**heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules**

1466E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.76	24.97	Hospira Pty Limited [PF]

▪ **NADROPARIN**

**nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10685J <b>NP</b>	10	..	..	*82.55	38.80	Fraxiparine [AS]

**nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10735B <b>NP</b>	10	..	..	*46.85	38.80	Fraxiparine [AS]

**nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10734Y <b>NP</b>	5	1	..	*82.60	38.80	Fraxiparine [AS]

**nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10716B <b>NP</b>	10	..	..	*118.35	38.80	Fraxiparine [AS]

**nadroparin calcium 15 200 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10725L <b>NP</b>	5	1	..	*154.10	38.80	Fraxiparine Forte [AS]

**nadroparin calcium 11 400 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10706L <b>NP</b>	5	1	..	*118.35	38.80	Fraxiparine Forte [AS]

**nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10686K <b>NP</b>	10	..	..	*64.75	38.80	Fraxiparine [AS]

**nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10707M <b>NP</b>	5	1	..	*189.85	38.80	Fraxiparine Forte [AS]

**nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10702G <b>NP</b>	5	1	..	*100.50	38.80	Fraxiparine [AS]

▪ **NADROPARIN**

**Restricted benefit**

Haemodialysis

**nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10717C <b>NP</b>	10	3	..	*82.55	38.80	Fraxiparine [AS]

**nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10687L <b>NP</b>	10	3	..	*46.85	38.80	Fraxiparine [AS]

**nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10740G <b>NP</b>	10	3	..	*154.05	38.80	Fraxiparine [AS]

**nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10718D <b>NP</b>	10	3	..	*118.35	38.80	Fraxiparine [AS]

**nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10701F <b>NP</b>	10	3	..	*64.75	38.80	Fraxiparine [AS]

**nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes**

10733X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	10	3	..	*189.85	38.80	Fraxiparine [AS]

*Platelet aggregation inhibitors excl. heparin*

▪ **ABCIXIMAB**

**Authority required (STREAMLINED)**

**4942**

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary balloon angioplasty.

**Authority required (STREAMLINED)**

**4943**

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary atherectomy.

**Authority required (STREAMLINED)**

**4915**

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary stent placement.

**abciximab 10 mg/5 mL injection, 5 mL vial**

8048N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1376.14	38.80	ReoPro [JC]

▪ **ASPIRIN**

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 300 mg effervescent tablet, 96**

1010E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.61	13.82	Solprin [RC]

▪ **ASPIRIN**

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 100 mg tablet, 112**

8202Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.93	14.14	Spren 100 [OW]

▪ **CLOPIDOGREL**

**Note** Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4166**

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The treatment must be in combination with aspirin.

**Authority required (STREAMLINED)**

**4165**

Cardiac stent insertion

**Clinical criteria:**

- The treatment must be in combination with aspirin, **AND**
- The treatment must follow insertion of a cardiac stent.

**clopidogrel 75 mg tablet, 28**

2275R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.18	16.39	<sup>a</sup> Clopidogrel-GA [EA] <sup>a</sup> Plidogrel [RF]	<sup>a</sup> Clovix 75 [RW]

**clopidogrel 75 mg tablet, 28**

9317J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.18	16.39	<sup>a</sup> APO-Clopidogrel [TX]	<sup>a</sup> Blooms the Chemist Clopidogrel [IB]
						<sup>a</sup> Chem mart Clopidogrel [CH]	<sup>a</sup> Clopidogrel AN [EA]
						<sup>a</sup> Clopidogrel Winthrop [WA]	<sup>a</sup> Iscover [AV]
						<sup>a</sup> Piax [AF]	<sup>a</sup> Plavix [SW]
						<sup>a</sup> Terry White Chemists Clopidogrel [TW]	

■ **CLOPIDOGREL**

**Note** Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5517**

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

**Authority required (STREAMLINED)**

**5524**

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Authority required (STREAMLINED)**

**5525**

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

**Authority required (STREAMLINED)**

**5459**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must have a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin.

**Authority required (STREAMLINED)**

**5436**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Authority required (STREAMLINED)**

**5508**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

**clopidogrel 75 mg tablet, 28**

5436D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.18	16.39	<sup>a</sup> Clopidogrel-DRLA [RZ]	

**clopidogrel 75 mg tablet, 28**

8358X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.18	16.39	<sup>a</sup> APO-Clopidogrel [TX]	<sup>a</sup> Blooms the Chemist Clopidogrel [IB]
						<sup>a</sup> Chem mart Clopidogrel [CH]	<sup>a</sup> Clopidogrel AN [EA]
						<sup>a</sup> Clopidogrel RBX [RA]	<sup>a</sup> Clopidogrel Sandoz [SZ]
						<sup>a</sup> Clopidogrel Winthrop [WA]	<sup>a</sup> Iscover [AV]
						<sup>a</sup> Piax [AF]	<sup>a</sup> Plavacor 75 [CR]
						<sup>a</sup> Plavix [SW]	<sup>a</sup> Terry White Chemists Clopidogrel [TW]

**clopidogrel 75 mg tablet, 28**

9354H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.18	16.39	<sup>a</sup> Clopidogrel-GA [EA] <sup>a</sup> Clovix 75 [RW]	<sup>a</sup> Clopidogrel GH [GQ] <sup>a</sup> Plidogrel [RF]

▪ **CLOPIDOGREL + ASPIRIN**

**Note** Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5488**

Acute coronary syndrome (myocardial infarction or unstable angina)

**Authority required (STREAMLINED)**

**5443**

Cardiac stent insertion

**Clinical criteria:**

- The treatment must follow insertion of a cardiac stent.

**Authority required (STREAMLINED)**

**5517**

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**clopidogrel 75 mg + aspirin 100 mg tablet, 30**

9296G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.47	16.68	<sup>a</sup> APO-Clopidogrel/Aspirin 75/100 [TX] <sup>a</sup> Clopidogrel/Aspirin Actavis 75/100 [EA] <sup>a</sup> Clopidogrel Winthrop plus aspirin [WA] <sup>a</sup> DuoCover [AV] <sup>a</sup> Piax Plus Aspirin [AF]	<sup>a</sup> Chem mart Clopidogrel/Aspirin 75/100 [CH] <sup>a</sup> Clopidogrel/Aspirin Sandoz 75/100 [SZ] <sup>a</sup> CoPlavix [SW] <sup>a</sup> DuoPlidogrel [GZ] <sup>a</sup> Terry White Chemists Clopidogrel/Aspirin 75/100 [TW]

▪ **DIPYRIDAMOLE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- The treatment must be as adjunctive therapy with low-dose aspirin.

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must be one in whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

**dipyridamole 200 mg modified release capsule, 60**

8335Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	36.32	37.53	Persantin SR [BY]

▪ **DIPYRIDAMOLE + ASPIRIN**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**dipyridamole 200 mg + aspirin 25 mg modified release capsule, 60**

8382E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	33.57	34.78	<sup>a</sup> Asasantin SR [BY]	<sup>a</sup> Diasp SR [RW]

▪ **EPTIFIBATIDE**

**Authority required (STREAMLINED)**

**6435**

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing non-urgent percutaneous intervention with intracoronary stenting.

**eptifibatide 75 mg/100 mL injection, 100 mL vial**

8684C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*963.40	38.80	Integrilin [MK]

**eptifibatide 20 mg/10 mL injection, 10 mL vial**

8683B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*238.91	38.80	Integrilin [MK]

▪ **PRASUGREL**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6454**

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The treatment must be managed by percutaneous coronary intervention in combination with aspirin.

**prasugrel 5 mg tablet, 28**

9495R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	88.83	38.80	Effient [LY]

**prasugrel 10 mg tablet, 28**

9496T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	97.46	38.80	Effient [LY]

▪ **TICAGRELOR**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5746**

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The treatment must be in combination with aspirin.

**TICAGRELOR Tablet 90 mg, 56**

1418P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	140.71	38.80	Brilinta [AP]

▪ **TIROFIBAN**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5782**

High risk of unstable angina

**Clinical criteria:**

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.

**Authority required (STREAMLINED)**

**5809**

High risk of unstable angina

**Clinical criteria:**

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

**Authority required (STREAMLINED)**

**5691**

Non-Q-wave myocardial infarction

**tirofiban 12.5 mg/50 mL injection, 50 mL vial**

8350L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	231.00	38.80	<sup>a</sup> Aggrastat [AS]	<sup>a</sup> Tirofiban AC [JO]

*Enzymes*

▪ **RETEPLASE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Acute myocardial infarction

**Clinical criteria:**

- The treatment must be administered within 6 hours of the onset of attack.

**reteplase 10 units (17.4 mg) injection [2 x 10 unit vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack**

8253J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	1965.61	38.80	Rapilysin 10 U [GN]

▪ **TENECTEPLASE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Acute myocardial infarction

**Clinical criteria:**

- The treatment must be administered within 12 hours of onset of attack.

**tenecteplase 8000 units (40 mg) injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack**

8526R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1861.19	38.80	Metalyse [BY]

**tenecteplase 10 000 units (50 mg) injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack**

8527T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1955.88	38.80	Metalyse [BY]

*Direct thrombin inhibitors*

▪ **BIVALIRUDIN**

**Authority required (STREAMLINED)**

**4919**

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary intervention.

**bivalirudin 250 mg injection, 1 vial**

8844L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	533.18	38.80	<sup>a</sup> Angiomax [XM]	<sup>a</sup> Bivalirudin APOTEX [TX]

▪ **DABIGATRAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4402**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**dabigatran etexilate 110 mg capsule, 60**

9321N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	88.38	38.80	Pradaxa [BY]

**dabigatran etexilate 75 mg capsule, 60**

9320M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	109.79	38.80	Pradaxa [BY]

▪ **DABIGATRAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4369**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 20 days supply to complete a course of treatment.

**dabigatran etexilate 75 mg capsule, 10**

9318K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*43.99	38.80	Pradaxa [BY]

**dabigatran etexilate 110 mg capsule, 10**

9319L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*36.85	38.06	Pradaxa [BY]

▪ **DABIGATRAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4381**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**dabigatran etexilate 75 mg capsule, 10**

9322P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*43.99	38.80	Pradaxa [BY]

**dabigatran etexilate 110 mg capsule, 10**

9323Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*36.85	38.06	Pradaxa [BY]

▪ **DABIGATRAN**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

## BLOOD AND BLOOD FORMING ORGANS

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

**Note** Special Pricing Arrangements apply.

### **Authority required (STREAMLINED)**

**4269**

Prevention of stroke or systemic embolism

#### **Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
  - Patient must have one or more risk factors for developing stroke or systemic embolism.
- Risk factors for developing stroke or systemic ischaemic embolism are:
- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
  - (ii) age 75 years or older;
  - (iii) hypertension;
  - (iv) diabetes mellitus;
  - (v) heart failure and/or left ventricular ejection fraction 35% or less.

### **dabigatran etexilate 110 mg capsule, 60**

2753X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.38	38.80	Pradaxa [BY]

### **dabigatran etexilate 150 mg capsule, 60**

2769R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.38	38.80	Pradaxa [BY]

### *Direct factor Xa inhibitors*

#### ▪ **APIXABAN**

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

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

#### **Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### **Authority required (STREAMLINED)**

**4402**

Prevention of venous thromboembolism

#### **Treatment criteria:**

- Patient must be undergoing total hip replacement.

#### **Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

### **apixaban 2.5 mg tablet, 60**

5061J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	92.92	38.80	Eliquis [BQ]

#### ▪ **APIXABAN**

#### **Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

### **Authority required (STREAMLINED)**

**4098**

Deep vein thrombosis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

### **Authority required (STREAMLINED)**

**5098**

Pulmonary embolism

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablets, 28**

10414D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	49.28	38.80	Eliquis [BQ]

**■ APIXABAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4382**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 15 days of therapy.

**Authority required (STREAMLINED)****4409**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 15 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 30**

5054B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	52.01	38.80	Eliquis [BQ]

**■ APIXABAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4381**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**Authority required (STREAMLINED)****4359**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 10 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 20**

5500L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	38.37	38.80	Eliquis [BQ]

**■ APIXABAN****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

**Authority required (STREAMLINED)****4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
  - Patient must have one or more risk factors for developing stroke or systemic embolism.
- Risk factors for developing stroke or systemic ischaemic embolism are:
- Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
  - age 75 years or older;
  - hypertension;
  - diabetes mellitus;
  - heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**4132**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**apixaban 2.5 mg tablet, 60**

2744K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	92.92	38.80	Eliquis [BQ]

▪ **APIXABAN**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

**Authority required (STREAMLINED)**

**4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
  - Patient must have one or more risk factors for developing stroke or systemic embolism.
- Risk factors for developing stroke or systemic ischaemic embolism are:
- Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
  - age 75 years or older;
  - hypertension;
  - diabetes mellitus;
  - heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**4099**

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

**5083**

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 60**

2735Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	92.92	38.80	Eliquis [BQ]

▪ **RIVAROXABAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4369**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 20 days supply to complete a course of treatment.

**rivaroxaban 10 mg tablet, 10**

9465E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	38.26	38.80	Xarelto [BN]

▪ **RIVAROXABAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4402**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**rivaroxaban 10 mg tablet, 15**

9466F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	51.85	38.80	Xarelto [BN]

**RIVAROXABAN Tablet 10 mg, 30**

9467G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	92.60	38.80	Xarelto [BN]

▪ **RIVAROXABAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4381**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**rivaroxaban 10 mg tablet, 10**

9468H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	38.26	38.80	Xarelto [BN]

▪ **RIVAROXABAN**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4382**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 15 days of therapy.

**rivaroxaban 10 mg tablet, 15**

9469J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	51.85	38.80	Xarelto [BN]

▪ **RIVAROXABAN**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
  - Patient must have one or more risk factors for developing stroke or systemic embolism.
- Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 15 mg tablet, 28**

2691P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	87.17	38.80	Xarelto [BN]

▪ **RIVAROXABAN**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

**Authority required (STREAMLINED)**

**4098**

Deep vein thrombosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

**4260**

Pulmonary embolism

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**Note** Special Pricing Arrangements apply.

**rivaroxaban 15 mg tablet, 42**

2160Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	125.21	38.80	Xarelto [BN]

▪ **RIVAROXABAN**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

**Authority required (STREAMLINED)**

**4099**

Deep vein thrombosis  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

**4132**

Prevention of recurrent venous thromboembolism  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED)**

**4268**

Pulmonary embolism  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**rivaroxaban 20 mg tablet, 28**

2268J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	87.17	38.80	Xarelto [BN]

*Other antithrombotic agents*

▪ **FONDAPARINUX**

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5781**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing major hip surgery.

**Authority required (STREAMLINED)**

**5808**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2**

8775W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3.5	..	..	*127.04	38.80	Arixtra [AS]

▪ **ANTIHEMORRHAGICS**

**ANTIFIBRINOLYTICS**

*Amino acids*

▪ **TRANEXAMIC ACID**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**tranexamic acid 500 mg tablet, 100**

2180R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	43.61	38.80	<sup>a</sup> APO-Tranexamic Acid [TX]	<sup>a</sup> Cyklokapron [PF]

▪ **ANTIANEMIC PREPARATIONS**

**IRON PREPARATIONS**

*Iron bivalent, oral preparations*

▪ **FERROUS FUMARATE**

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60**

8985X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.76	18.97	Ferro-tab [AE]

▪ **FERROUS SULFATE**

**ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL**

8815Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	21.77	22.98	Ferro-Liquid [AE]

*Iron, parenteral preparations*

▪ **IRON**

**iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial**

10104T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*307.49	38.80	ferinject [VL]

▪ **IRON POLYMALTOSE**

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

2593L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.69	24.90	Ferrosig [SI]

▪ **IRON POLYMALTOSE**

**Authority required (STREAMLINED)**

**4302**

Iron deficiency anaemia

**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

2805P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.69	24.90	Ferrosig [SI]

▪ **IRON SUCROSE**

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

10229J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	40.06	38.80	Venofer [AS]

▪ **IRON SUCROSE**

**Authority required (STREAMLINED)**

**4302**

Iron deficiency anaemia

**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

8807M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	5	..	40.06	38.80	Venofer [AS]	

*Iron in combination with folic acid***■ FERROUS FUMARATE + FOLIC ACID****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60**

9011G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	1	..	18.78	19.99	Ferro-f-tab [AE]	

**VITAMIN B12 AND FOLIC ACID***Vitamin B12 (cyanocobalamin and analogues)***■ HYDROXOCOBALAMIN**

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B<sub>12</sub> deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Restricted benefit**

Pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

2162T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	15.36	16.57	<sup>a</sup> Cobal-B12 [JU]	<sup>a</sup> Vita-B12 [GH]

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

9048F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	15.36	16.57	<sup>a</sup> Hydroxo-B12 [AS]	<sup>a</sup> Neo-B12 [PF]

*Folic acid and derivatives***■ FOLIC ACID****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 500 microgram tablet, 100**

2958Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*15.15	16.36	<sup>a</sup> Foltabs 500 [PP]	<sup>a</sup> Megafol 0.5 [AF]

**■ FOLIC ACID**

**Note** The 5 mg strength tablet should be used in malabsorption states only.

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 5 mg tablet, 100**

1437P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	1	..	*17.37	18.58	Megafol 5 [AF]	

■ **BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS**

**BLOOD AND RELATED PRODUCTS**

*Blood substitutes and plasma protein fractions*

■ **PENTASTARCH + SODIUM CHLORIDE**

**HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1**

9487H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	..	..	*44.17	38.80	Voluven 6% [PK]

■ **SUCCINYLATED GELATIN**

**succinylated gelatin 20 g/500 mL injection, 500 mL bag**

8444K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	..	..	*44.17	38.80	Gelofusine [BR]

■ **OTHER HEMATOLOGICAL AGENTS**

**OTHER HEMATOLOGICAL AGENTS**

*Drugs used in hereditary angioedema*

■ **ICATIBANT**

**Note** Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at [www.allergy.org.au](http://www.allergy.org.au))

**Authority required**

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, **AND**
- Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, **AND**
- The condition must be assessed by a clinical immunologist; OR
- The condition must be assessed by a respiratory physician; OR
- The condition must be assessed by a specialist allergist; OR
- The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.

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

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Increased maximum quantities will be limited to 12 injections per authority prescription.

**Authority required**

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

**Clinical criteria:**

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

Increased maximum quantities will be limited to 12 injections per authority prescription.

**ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1**

1976B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	2574.52	38.80	Firazyr [ZI]

■ **CARDIOVASCULAR SYSTEM**

■ **CARDIAC THERAPY**

**CARDIAC GLYCOSIDES**

*Digitalis glycosides*

■ **DIGOXIN**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**digoxin 50 microgram/mL oral liquid, 60 mL**

3164M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*41.29	38.80	Lanoxin [QA]

**digoxin 62.5 microgram tablet, 200**

2605D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	14.57	15.78	<sup>a</sup> Sigmaxin-PG [FM]
			<sup>b</sup> 2.56	17.13	15.78	<sup>a</sup> Lanoxin-PG [QA]

**digoxin 250 microgram tablet, 100**

1322N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	14.82	16.03	<sup>a</sup> Sigmaxin [FM]
			<sup>b</sup> 2.56	17.38	16.03	<sup>a</sup> Lanoxin [QA]

**ANTIARRHYTHMICS, CLASS I AND III**

*Antiarrhythmics, class Ia*

▪ **DISOPYRAMIDE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**disopyramide 100 mg capsule, 100**

2923W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	29.85	31.06	Rythmodan [SW]

*Antiarrhythmics, class Ib*

▪ **LIGNOCAINE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules**

2876J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	30.23	31.44	Xylocard 500 [AS]

*Antiarrhythmics, class Ic*

▪ **FLECAINIDE**

**Caution** Flecainide acetate should be avoided in patients with poor cardiac function.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Serious supra-ventricular cardiac arrhythmias

**Restricted benefit**

Serious ventricular cardiac arrhythmias

**Clinical criteria:**

- The treatment must be initiated in a hospital.

**flecainide acetate 100 mg tablet, 60**

1090J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	39.45	38.80	<sup>a</sup> Flecainide Sandoz [SZ]	<sup>a</sup> Flecatag [AF]
						<sup>a</sup> Tambocor [IA]	

**flecainide acetate 50 mg tablet, 60**

1088G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.97	35.18	<sup>a</sup> Flecainide Sandoz [SZ]	<sup>a</sup> Tambocor [IA]

*Antiarrhythmics, class III*

▪ **AMIODARONE**

**Note** This drug has been reported to cause frequent and potentially serious toxicity.

**Note** Regular monitoring of hepatic and thyroid function is recommended.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Severe cardiac arrhythmias

**amiodarone hydrochloride 100 mg tablet, 30**

2344J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.44	16.65	<sup>a</sup> Aratac 100 [AF]	<sup>a</sup> Cordarone X 100 [SW]

**amiodarone hydrochloride 200 mg tablet, 30**

2343H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.83	20.04	<sup>a</sup> Amiodarone Sandoz [SZ] <sup>a</sup> Cordarone X 200 [SW] <sup>a</sup> Rithmik 200 [RW]	<sup>a</sup> Aratac 200 [AF] <sup>a</sup> GenRx Amiodarone [GX]

▪ **SOTALOL**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Severe cardiac arrhythmias

**sotalol hydrochloride 160 mg tablet, 60**

2043M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.00	19.21	<sup>a</sup> APO-Sotalol [TX] <sup>a</sup> Solavert [RF]	<sup>a</sup> Cardol [AF] <sup>a</sup> Sotalol Sandoz [SZ]
			<sup>b</sup> 4.33	22.33	19.21	<sup>a</sup> Sotacor [RW]	

**sotalol hydrochloride 80 mg tablet, 60**

8398B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.30	15.51	<sup>a</sup> APO-Sotalol [TX] <sup>a</sup> Solavert [RF]	<sup>a</sup> Cardol [AF] <sup>a</sup> Sotalol Sandoz [SZ]
			<sup>b</sup> 4.33	18.63	15.51	<sup>a</sup> Sotacor [RW]	

**CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES**

*Adrenergic and dopaminergic agents*

▪ **ADRENALINE**

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

1016L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	22.58	23.79	Link Medical Products Pty Ltd [LM]

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

5004J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	22.58	23.79	Link Medical Products Pty Ltd [LM]

▪ **ADRENALINE**

**Caution** EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

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

**Note** Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

**Note** No applications for repeats will be authorised.

**Authority required**

Acute allergic reaction with anaphylaxis

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

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
  - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
  - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
  - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.
- The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**

Acute allergic reaction with anaphylaxis

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

**Clinical criteria:**

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

**Authority required**

Acute allergic reaction with anaphylaxis

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

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**adrenaline 300 microgram/0.3 mL injection, 1 dose**

8698T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	97.10	38.80	EpiPen [AL]

**adrenaline 150 microgram/0.3 mL injection, 1 dose**

8697R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	97.10	38.80	EpiPen Jr. [AL]

**VASODILATORS USED IN CARDIAC DISEASES**

*Organic nitrates*

▪ **GLYCERYL TRINITRATE**

**glyceryl trinitrate 5 mg/24 hours patch, 30**

1515R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	27.31	28.52	Transiderm-Nitro 25 [SZ]

**glyceryl trinitrate 5 mg/24 hours patch, 30**

8010N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	27.31	28.52	Nitro-Dur 5 [MK]

**glyceryl trinitrate 5 mg/24 hours patch, 30**

8027L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	27.31	28.52	Minitran 5 [IA]

**glyceryl trinitrate 600 microgram sublingual tablet, 100**

1459T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	18.40	19.61	Nitrostat [PF]
						<sup>a</sup> Lycinat [RF]
			<sup>b</sup> 2.56	20.96	19.61	<sup>a</sup> Anginine Stabilised [RW]

**glyceryl trinitrate 600 microgram sublingual tablet, 100**

5108W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	18.40	19.61	Nitrostat [PF]
						<sup>a</sup> Lycinat [RF]
			<sup>b</sup> 2.56	20.96	19.61	<sup>a</sup> Anginine Stabilised [RW]

**glyceryl trinitrate 10 mg/24 hours patch, 30**

1516T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	32.36	33.57	Transiderm-Nitro 50 [SZ]

**glyceryl trinitrate 10 mg/24 hours patch, 30**

8011P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	32.36	33.57	Nitro-Dur 10 [MK]

**glyceryl trinitrate 10 mg/24 hours patch, 30**

8028M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	32.36	33.57	Minitran 10 [IA]

**glyceryl trinitrate 300 microgram sublingual tablet, 100**

11027J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	18.40	19.61	Nitrostat [PF]

**glyceryl trinitrate 300 microgram sublingual tablet, 100**

11051P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	18.40	19.61	Nitrostat [PF]

**glyceryl trinitrate 15 mg/24 hours patch, 30**

8026K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	5	..	32.36	33.57	Nitro-Dur 15 [MK]	

**glyceryl trinitrate 15 mg/24 hours patch, 30**

8119H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	5	..	32.36	33.57	Minitran 15 [IA]	

■ **GLYCERYL TRINITRATE**

**Note** The spray should not be inhaled.

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

8171C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	‡1	5	..	23.01	24.22	Nitrolingual Pumpspray [SW]	

■ **ISOSORBIDE DINITRATE**

**isosorbide dinitrate 5 mg sublingual tablet, 100**

2588F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	2	..	*18.17	19.38	Isordil Sublingual [RW]	

■ **ISOSORBIDE MONONITRATE**

**isosorbide mononitrate 60 mg modified release tablet, 30**

1558B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14.77	15.98	<sup>a</sup> Chem mart Isosorbide Mononitrate [CH]	<sup>a</sup> Duride [AF]
						<sup>a</sup> GenRx Isosorbide Mononitrate [GX]	<sup>a</sup> Isomonit [SZ]
						<sup>a</sup> Isosorbide AN [EA]	<sup>a</sup> Terry White Chemists Isosorbide Mononitrate [TW]
			<sup>b</sup> 2.48	17.25	15.98	<sup>a</sup> Monodur 60 mg [PM]	
			<sup>b</sup> 3.37	18.14	15.98	<sup>a</sup> Imdur Durule [AP]	

**isosorbide mononitrate 120 mg modified release tablet, 30**

8273K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	5	..	18.41	19.62	<sup>a</sup> Monodur 120 mg [PM]	
			<sup>b</sup> 3.37	21.78	19.62	<sup>a</sup> Imdur 120 mg [AP]	

*Other vasodilators used in cardiac diseases*

■ **NICORANDIL**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**nicorandil 20 mg tablet, 60**

8229D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	30.56	31.77	<sup>a</sup> Ikorel [SW]	<sup>a</sup> Ikotab [QA]

**nicorandil 10 mg tablet, 60**

8228C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	25.07	26.28	<sup>a</sup> Ikorel [SW]	<sup>a</sup> Ikotab [QA]

■ **PERHEXILINE**

**Note** Regular monitoring of drug serum levels is recommended.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5592**

Angina

**Clinical criteria:**

- The condition must not be responding to other therapy.

**perhexiline maleate 100 mg tablet, 100**

1822X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.62	38.80	Pexsig [QA]

**OTHER CARDIAC PREPARATIONS**

*Other cardiac preparations*

▪ **IVABRADINE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4979**

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

**ivabradine 5 mg tablet, 56**

10012Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.25	38.80	Coralan [SE]

**ivabradine 7.5 mg tablet, 56**

2960T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.25	38.80	Coralan [SE]

▪ **ANTIHYPERTENSIVES**

**ANTIADRENERGIC AGENTS, CENTRALLY ACTING**

*Methyl dopa*

▪ **METHYLDOPA**

**methyl dopa 250 mg tablet, 100**

1629R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.89	21.10	<sup>a</sup> Hydopa [AF]
			<sup>B</sup> 3.08	22.97	21.10	<sup>a</sup> Aldomet [AS]

*Imidazoline receptor agonists*

▪ **CLONIDINE**

**clonidine hydrochloride 100 microgram tablet, 100**

3145M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.67	27.88	<sup>a</sup> APO-Clonidine [TX]	<sup>a</sup> Catapres 100 [BY]

**clonidine hydrochloride 150 microgram tablet, 100**

3141H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.62	33.83	Catapres [BY]

▪ **MOXONIDINE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

9019Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	21.92	23.13	Physiotens [GO]

# CARDIOVASCULAR SYSTEM

General

## moxonidine 400 microgram tablet, 30

9020R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	29.56	30.77	Physiotens [GO]

## ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

### Alpha-adrenoreceptor antagonists

#### ■ PRAZOSIN

##### prazosin 2 mg tablet, 100

1480X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.97	18.18	<sup>a</sup> APO-Prazosin [TX] <sup>a</sup> Minipress [PF]	<sup>a</sup> Chem mart Prazosin [CH] <sup>a</sup> Terry White Chemists Prazosin [TW]

##### prazosin 5 mg tablet, 100

1478T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.65	22.86	<sup>a</sup> APO-Prazosin [TX] <sup>a</sup> Minipress [PF]	<sup>a</sup> Chem mart Prazosin [CH] <sup>a</sup> Terry White Chemists Prazosin [TW]

##### prazosin 1 mg tablet, 100

1479W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.22	16.43	<sup>a</sup> APO-Prazosin [TX] <sup>a</sup> Minipress [PF]	<sup>a</sup> Chem mart Prazosin [CH] <sup>a</sup> Terry White Chemists Prazosin [TW]

## ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

### Hydrazinophthalazine derivatives

#### ■ HYDRALAZINE

##### hydralazine hydrochloride 50 mg tablet, 100

1639G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*21.51	22.72	Alphapress 50 [AF]

##### hydralazine hydrochloride 25 mg tablet, 100

1640H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*20.07	21.28	Alphapress 25 [AF]

### Pyrimidine derivatives

#### ■ MINOXIDIL

##### Note Continuing Therapy Only:

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

##### Restricted benefit

Severe refractory hypertension

##### Clinical criteria:

- The treatment must be initiated by a consultant physician.

##### minoxidil 10 mg tablet, 100

2313R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.59	38.80	Loniten [PF]

#### ■ DIURETICS

### LOW-CEILING DIURETICS, THIAZIDES

#### Thiazides, plain

#### ■ HYDROCHLOROTHIAZIDE

##### hydrochlorothiazide 25 mg tablet, 100

1484D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	23.34	24.55	Dithiazide [PL]

### LOW-CEILING DIURETICS, EXCL. THIAZIDES

#### Sulfonamides, plain

▪ **CHLORTHALIDONE**

**chlorthalidone 25 mg tablet, 50**

1585K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*20.29	21.50	Hygroton 25 [GH]

▪ **INDAPAMIDE**

**indapamide hemihydrate 1.5 mg modified release tablet, 90**

8532C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	18.80	20.01	<sup>a</sup> APO-Indapamide SR [TX]	<sup>a</sup> Chem mart Indapamide SR [CH]
						<sup>a</sup> INDAPAMIDE AN SR [EA]	<sup>a</sup> Odaplix SR [AF]
						<sup>a</sup> Tenaxil SR [RW]	<sup>a</sup> Terry White Chemists Indapamide SR [TW]
			<sup>B</sup> 4.95	23.75	20.01	<sup>a</sup> Natrilix SR [SE]	

**indapamide hemihydrate 2.5 mg tablet, 90**

2436F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	16.37	17.58	<sup>a</sup> Dapa-Tabs [AF]	<sup>a</sup> GenRx Indapamide [GX]
						<sup>a</sup> Indapamide AN [EA]	<sup>a</sup> Indapamide Sandoz [SZ]
						<sup>a</sup> Insig [RW]	
			<sup>B</sup> 4.95	21.32	17.58	<sup>a</sup> Natrilix [SE]	

**HIGH-CEILING DIURETICS**

*Sulfonamides, plain*

▪ **FRUSEMIDE**

**frusemide 10 mg/mL oral liquid, 30 mL**

2411X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	3	..	27.11	28.32	Lasix [SW]

**frusemide 500 mg tablet, 50**

2415D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	3	..	18.92	20.13	Urex-Forte [RW]

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

2413B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	13.24	14.45	<sup>a</sup> Frusemide-Clarix [AE]	<sup>a</sup> Frusemide Sandoz [SZ]
						<sup>a</sup> Lasix [SW]	

**frusemide 40 mg tablet, 100**

2412Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.77	13.98	Urex [RW]	
						<sup>a</sup> APO-Frusemide [TX]	<sup>a</sup> Chem mart Frusemide [CH]
						<sup>a</sup> Frusax [ER]	<sup>a</sup> Frusemide RBX [RA]
						<sup>a</sup> Frusemide Sandoz [SZ]	<sup>a</sup> FUROSEMIDE AN [EA]
						<sup>a</sup> Terry White Chemists Frusemide [TW]	<sup>a</sup> Uremide [AF]
			<sup>B</sup> 1.85	14.62	13.98	<sup>a</sup> Lasix [SW]	

▪ **FRUSEMIDE**

**Note** For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

**frusemide 20 mg tablet, 50**

1810G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*12.77	13.98	<sup>a</sup> Urex-M [RW]
			<sup>B</sup> 1.46	*14.23	13.98	<sup>a</sup> Lasix-M [SW]

**frusemide 20 mg tablet, 100**

2414C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.77	13.98	<sup>a</sup> APO-Frusemide [TX]	<sup>a</sup> Chem mart Frusemide [CH]
						<sup>a</sup> Frusemide RBX [RA]	<sup>a</sup> FUROSEMIDE AN [EA]
						<sup>a</sup> Terry White Chemists Frusemide [TW]	

*Aryloxyacetic acid derivatives*

▪ **ETHACRYNIC ACID**

**Restricted benefit**

Patients hypersensitive to other oral diuretics

**ethacrynic acid 25 mg tablet, 100**

8748K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*175.93	38.80	Edecrin [FK]

**POTASSIUM-SPARING AGENTS**

*Aldosterone antagonists*

▪ **EPLERENONE**

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4937**

Heart failure with a left ventricular ejection fraction of 40% or less

**Clinical criteria:**

- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
  - The treatment must be commenced within 14 days of an acute myocardial infarction.
- The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

**eplerenone 25 mg tablet, 30**

8879H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	88.24	38.80	<sup>a</sup> Eplerenone AN [EA] <sup>a</sup> Inpler [AF]	<sup>a</sup> ESPLER [RW] <sup>a</sup> Inspra [PF]

**eplerenone 50 mg tablet, 30**

8880J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	88.24	38.80	<sup>a</sup> Eplerenone AN [EA] <sup>a</sup> Inpler [AF]	<sup>a</sup> ESPLER [RW] <sup>a</sup> Inspra [PF]

▪ **SPIRONOLACTONE**

**Caution** Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**spironolactone 100 mg tablet, 100**

2340E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	.. <sup>B</sup> 7.49	30.83 38.32	32.04 32.04	<sup>a</sup> Spiractin 100 [AF] <sup>a</sup> Aldactone [PF]

**spironolactone 25 mg tablet, 100**

2339D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	.. <sup>B</sup> 7.50	16.11 23.61	17.32 17.32	<sup>a</sup> Spiractin 25 [AF] <sup>a</sup> Aldactone [PF]

**DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION**

*Low-ceiling diuretics and potassium-sparing agents*

▪ **AMILORIDE + HYDROCHLOROTHIAZIDE**

**Caution** Serum electrolytes should be checked regularly.

**amiloride hydrochloride 5 mg + hydrochlorothiazide 50 mg tablet, 50**

1486F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*17.25	18.46	Moduretic [AS]

▪ **HYDROCHLOROTHIAZIDE + TRIAMTERENE**

**Caution** Serum electrolytes should be checked regularly.

**hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100**

1280J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	16.72	17.93	Hydrene 25/50 [AF]

**PERIPHERAL VASODILATORS**

**PERIPHERAL VASODILATORS**

*Other peripheral vasodilators*

**PHENOXYBENZAMINE**

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Phaeochromocytoma

**Restricted benefit**

Neurogenic urinary retention

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

1862B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1103.27	38.80	Dibenziline [GH]

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

9286R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1103.27	38.80	Dibenziline [BZ]

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

1166J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*997.75	38.80	Amdipharm Mercury (Australia) Pty Limited [GH]

**BETA BLOCKING AGENTS**

**BETA BLOCKING AGENTS**

*Beta blocking agents, non-selective*

**OXPRENOLOL**

**oxprenolol hydrochloride 40 mg tablet, 100**

2961W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	46.54	38.80	Corbeton 40 [AF]

**PINDOLOL**

**pindolol 5 mg tablet, 100**

3062E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	31.97	33.18	Barbloc 5 [AF]

**PROPRANOLOL**

**propranolol hydrochloride 160 mg tablet, 50**

2899N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.81	19.02	Deralin 160 [AF]

**propranolol hydrochloride 10 mg tablet, 100**

2565B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	13.84	15.05	<sup>a</sup> APO-Propranolol [TX]
			<sup>b</sup> 2.99	16.83	15.05	<sup>a</sup> Deralin 10 [AF]
			<sup>b</sup> 3.75	17.59	15.05	<sup>a</sup> Inderal [AP]

**propranolol hydrochloride 40 mg tablet, 100**

2566C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.11	15.32	<sup>a</sup> APO-Propranolol [TX]
			<sup>b</sup> 2.99	17.10	15.32	<sup>a</sup> Deralin 40 [AF]
			<sup>b</sup> 3.75	17.86	15.32	<sup>a</sup> Inderal [AP]

*Beta blocking agents, selective*

■ **ATENOLOL**

**atenolol 50 mg tablet, 30**

1081X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.23	13.44	<sup>a</sup> APO-Atenolol [TX] <sup>a</sup> Atenolol-GA [ED] <sup>a</sup> Atenolol RBX [RA] <sup>a</sup> Chem mart Atenolol [CH] <sup>a</sup> Tenolten 50 [DO] <sup>a</sup> Terry White Chemists Atenolol [TW]	<sup>a</sup> Atenolol Amneal [EF] <sup>a</sup> Atenolol GH [GQ] <sup>a</sup> Atenolol Sandoz [SZ] <sup>a</sup> Noten [AF] <sup>a</sup> Tensig [RW]
			<sup>b</sup> 2.44	14.67	13.44	<sup>a</sup> Tenormin [AP]	

■ **ATENOLOL**

**Restricted benefit**

For a patient who is unable to take a solid dose form of atenolol.

**atenolol 50 mg/10 mL oral liquid, 300 mL**

2243C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	29.37	30.58	Atenolol-AFT [AE]

■ **BISOPROLOL**

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**bisoprolol fumarate 2.5 mg tablet, 28**

8604W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.84	19.05	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bicard 2.5 [RW] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> Bispro 2.5 [AF] <sup>a</sup> Terry White Chemists Bisoprolol [TW]	<sup>a</sup> Beprol 2.5 [DO] <sup>a</sup> Bisoprolol AN [EA] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Chem mart Bisoprolol [CH]
			<sup>b</sup> 5.88	23.72	19.05	<sup>a</sup> Bicolor [AL]	

**bisoprolol fumarate 10 mg tablet, 28**

8606Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.63	22.84	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bicard 10 [RW] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> Bispro 10 [AF] <sup>a</sup> Terry White Chemists Bisoprolol [TW]	<sup>a</sup> Beprol 10 [DO] <sup>a</sup> Bisoprolol AN [EA] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Chem mart Bisoprolol [CH]
			<sup>b</sup> 5.88	27.51	22.84	<sup>a</sup> Bicolor [AL]	

**bisoprolol fumarate 5 mg tablet, 28**

8605X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.52	20.73	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bicard 5 [RW] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> Bispro 5 [AF] <sup>a</sup> Terry White Chemists Bisoprolol [TW]	<sup>a</sup> Beprol 5 [DO] <sup>a</sup> Bisoprolol AN [EA] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Chem mart Bisoprolol [CH]
			<sup>b</sup> 5.87	25.39	20.73	<sup>a</sup> Bicolor [AL]	

■ **METOPROLOL SUCCINATE**

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30**

8733P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	50.07	38.80	<sup>a</sup> Metrol-XL 47.5 [RW] <sup>a</sup> Toprol-XL 47.5 [AP]	<sup>a</sup> Minax XL [AF]

**METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30**

8734Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	59.80	38.80	<sup>a</sup> Metrol-XL 95 [RW] <sup>a</sup> Toprol-XL 95 [AP]	<sup>a</sup> Minax XL [AF]

**METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15**

8732N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	19.35	20.56	<sup>a</sup> Metrol-XL 23.75 [RW] <sup>a</sup> Toprol-XL 23.75 [AP]	<sup>a</sup> Minax XL [AF]

**METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30**

8735R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	71.97	38.80	<sup>a</sup> Metrol-XL 190 [RW] <sup>a</sup> Toprol-XL 190 [AP]	<sup>a</sup> Minax XL [AF]

▪ **METOPROLOL TARTRATE**

**METOPROLOL TARTRATE Tablet 100 mg, 60**

1325R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.52	14.73	<sup>a</sup> Metoprolol AN [EA] <sup>a</sup> Mistrom [ER] <sup>b</sup> APO-Metoprolol [TX] <sup>b</sup> Metoprolol Sandoz [SZ] <sup>b</sup> Minax 100 [AF]	<sup>a</sup> Metoprolol RBX [RA]  <sup>b</sup> Chem mart Metoprolol [CH] <sup>b</sup> Metrol 100 [RW] <sup>b</sup> Terry White Chemists Metoprolol [TW]
			<sup>b</sup> 1.80	15.32	14.73	<sup>a</sup> Lopresor 100 [NV]	
			<sup>b</sup> 3.76	17.28	14.73	<sup>b</sup> Betaloc [AP]	

**METOPROLOL TARTRATE Tablet 50 mg, 100**

1324Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.99	14.20	<sup>a</sup> Metoprolol AN [EA] <sup>a</sup> Mistrom [ER] <sup>b</sup> APO-Metoprolol [TX] <sup>b</sup> Metoprolol Sandoz [SZ] <sup>b</sup> Minax 50 [AF]	<sup>a</sup> Metoprolol RBX [RA]  <sup>b</sup> Chem mart Metoprolol [CH] <sup>b</sup> Metrol 50 [RW] <sup>b</sup> Terry White Chemists Metoprolol [TW]
			<sup>b</sup> 1.80	14.79	14.20	<sup>a</sup> Lopresor 50 [NV]	
			<sup>b</sup> 3.76	16.75	14.20	<sup>b</sup> Betaloc [AP]	

▪ **NEBIVOLOL**

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**nebivolol 5 mg tablet, 28**

9311C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.17	38.80	Nebilet [FK]

**nebivolol 1.25 mg tablet, 28**

9316H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*48.81	38.80	Nebilet [FK]

**nebivolol 10 mg tablet, 28**

9312D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	64.29	38.80	Nebilet [FK]

*Alpha and beta blocking agents*

▪ **CARVEDILOL**

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**Restricted benefit**

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**carvedilol 6.25 mg tablet, 60**

8256M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.70	20.91	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> Carvedilol Sandoz [SZ]  <sup>a</sup> Dicarz [AF] <sup>a</sup> Terry White Chemists Carvedilol 6.25 mg [TW] <sup>a</sup> Volirop 6.25 [DO]	<sup>a</sup> Carvedilol AN [EA] <sup>a</sup> Chem mart Carvedilol 6.25 mg [CH] <sup>a</sup> Dilatrend 6.25 [PB] <sup>a</sup> Vedilol 6.25 [RW]

**carvedilol 25 mg tablet, 60**

8258P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	24.55	25.76	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> Carvedilol Sandoz [SZ]  <sup>a</sup> Dicarz [AF] <sup>a</sup> Terry White Chemists Carvedilol 25 mg [TW] <sup>a</sup> Volirop 25 [DO]	<sup>a</sup> Carvedilol AN [EA] <sup>a</sup> Chem mart Carvedilol 25 mg [CH] <sup>a</sup> Dilatrend 25 [PB] <sup>a</sup> Vedilol 25 [RW]

**carvedilol 12.5 mg tablet, 60**

8257N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.86	23.07	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> Carvedilol Sandoz [SZ]  <sup>a</sup> Dicarz [AF] <sup>a</sup> Terry White Chemists Carvedilol 12.5 mg [TW] <sup>a</sup> Volirop 12.5 [DO]	<sup>a</sup> Carvedilol AN [EA] <sup>a</sup> Chem mart Carvedilol 12.5 mg [CH] <sup>a</sup> Dilatrend 12.5 [PB] <sup>a</sup> Vedilol 12.5 [RW]

**carvedilol 3.125 mg tablet, 30**

8255L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	14.13	15.34	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> Chem mart Carvedilol 3.125 mg [CH] <sup>a</sup> Vedilol 3.125 [RW]	<sup>a</sup> Carvedilol AN [EA] <sup>a</sup> Terry White Chemists Carvedilol 3.125 mg [TW] <sup>a</sup> Volirop 3.125 [DO]

▪ **LABETALOL**

**labetalol hydrochloride 100 mg tablet, 100**

1566K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	24.34	25.55	<sup>a</sup> Presolol 100 [AF]
			<sup>B</sup> 3.50	27.84	25.55	<sup>a</sup> Trandate [QA]

**labetalol hydrochloride 200 mg tablet, 100**

1567L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	24.34	25.55	<sup>a</sup> Presolol 200 [AF]
			<sup>B</sup> 3.50	27.84	25.55	<sup>a</sup> Trandate [QA]

**■ CALCIUM CHANNEL BLOCKERS**  
**SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS**  
*Dihydropyridine derivatives*

**■ AMLODIPINE**

**amlodipine 10 mg tablet, 30**

2752W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.67	13.88	<sup>a</sup> Amlodipine AN [EA] <sup>a</sup> Amlodipine Sandoz [SZ] <sup>a</sup> Auro-Amlodipine 10 [DO] <sup>a</sup> Chem mart Amlodipine [CH] <sup>a</sup> Norvapine [ED] <sup>a</sup> Pharmacor Amlodipine [CR]	<sup>a</sup> Amlodipine Amneal [EF] <sup>a</sup> Amlodipine GH [GQ] <sup>a</sup> APO-Amlodipine [TX] <sup>a</sup> Blooms the Chemist Amlodipine [IB] <sup>a</sup> Nordip [AF] <sup>a</sup> Ozlodip [RA] <sup>a</sup> Terry White Chemists Amlodipine [TW]
			<sup>b</sup> 9.20	21.87	13.88	<sup>a</sup> Norvasc [PF]	

**amlodipine 5 mg tablet, 30**

2751T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.98	13.19	<sup>a</sup> Amlodipine AN [EA] <sup>a</sup> Amlodipine Sandoz [SZ] <sup>a</sup> Auro-Amlodipine 5 [DO] <sup>a</sup> Chem mart Amlodipine [CH] <sup>a</sup> Norvapine [ED] <sup>a</sup> Pharmacor Amlodipine [CR]	<sup>a</sup> Amlodipine Amneal [EF] <sup>a</sup> Amlodipine GH [GQ] <sup>a</sup> APO-Amlodipine [TX] <sup>a</sup> Blooms the Chemist Amlodipine [IB] <sup>a</sup> Nordip [AF] <sup>a</sup> Ozlodip [RA] <sup>a</sup> Terry White Chemists Amlodipine [TW]
			<sup>b</sup> 9.20	21.18	13.19	<sup>a</sup> Norvasc [PF]	

**■ FELODIPINE**

**felodipine 5 mg modified release tablet, 30**

2366M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.12	16.33	<sup>a</sup> Felodil XR 5 [RW] <sup>a</sup> Fendex ER [AF]	<sup>a</sup> Felodur ER 5 mg [TX]
			<sup>b</sup> 2.09	17.21	16.33	<sup>a</sup> Plendil ER [GX]	

**felodipine 10 mg modified release tablet, 30**

2367N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.39	19.60	<sup>a</sup> Felodil XR 10 [RW] <sup>a</sup> Fendex ER [AF]	<sup>a</sup> Felodur ER 10 mg [TX]
			<sup>b</sup> 2.09	20.48	19.60	<sup>a</sup> Plendil ER [GX]	

**felodipine 2.5 mg modified release tablet, 30**

2361G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.90	15.11	<sup>a</sup> Felodur ER 2.5 mg [TX]	<sup>a</sup> Fendex ER [AF]
			<sup>b</sup> 2.08	15.98	15.11	<sup>a</sup> Plendil ER [GX]	

**■ LERCANIDIPINE**

**lercanidipine hydrochloride 20 mg tablet, 28**

8679T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.58	15.79	<sup>a</sup> APO-Lercanidipine [TX] <sup>a</sup> Chem mart Lercanidipine [CH] <sup>a</sup> Lercadip [EA] <sup>a</sup> Lercanidipine GH [GQ] <sup>a</sup> Terry White Chemists Lercanidipine [TW]	<sup>a</sup> Blooms the Chemist Lercanidipine [IB] <sup>a</sup> Ledip [RA] <sup>a</sup> Lercan [RW] <sup>a</sup> Lercanidipine Sandoz [SZ] <sup>a</sup> Zircol [AF]
			<sup>b</sup> 2.77	17.35	15.79	<sup>a</sup> Zanidip [GO]	

**lercanidipine hydrochloride 10 mg tablet, 28**

8534E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.19	14.40	<sup>a</sup> APO-Lercanidipine [TX] <sup>a</sup> Chem mart Lercanidipine [CH]	<sup>a</sup> Blooms the Chemist Lercanidipine [IB] <sup>a</sup> Ledip [RA]

<sup>a</sup> Lercadip [EA]  
<sup>a</sup> Lercanidipine GH [GQ]  
<sup>a</sup> Terry White Chemists Lercanidipine [TW]  
<sup>a</sup> Zanidip [GO]  
<sup>a</sup> Lercan [RW]  
<sup>a</sup> Lercanidipine Sandoz [SZ]  
<sup>a</sup> Zircol [AF]

<sup>B</sup>2.76 15.95 14.40

■ NIFEDIPINE

**nifedipine 20 mg modified release tablet, 30**

8610E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.47	18.68	Adalat Oros 20mg [BN]
			<sup>B</sup> 2.76	15.95	14.40	

**nifedipine 10 mg tablet, 60**

1694E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.08	17.29	<sup>a</sup> Adefin 10 [AF]
			<sup>B</sup> 1.64	17.72	17.29	<sup>a</sup> Adalat 10 [BN]

**nifedipine 20 mg tablet, 60**

1695F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.23	18.44	<sup>a</sup> Adefin 20 [AF]
			<sup>B</sup> 2.29	19.52	18.44	<sup>a</sup> Adalat 20 [BN]

**nifedipine 30 mg modified release tablet, 30**

1906H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.98	19.19	<sup>a</sup> Addos XR 30 [RW]	<sup>a</sup> Adefin XL 30 [AF]
			<sup>B</sup> 2.52	20.50	19.19	<sup>a</sup> APO-Nifedipine XR [TX]	<sup>a</sup> Adalat Oros 30 [BN]

**nifedipine 60 mg modified release tablet, 30**

1907J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.75	20.96	<sup>a</sup> Addos XR 60 [RW]	<sup>a</sup> Adefin XL 60 [AF]
			<sup>B</sup> 2.66	22.41	20.96	<sup>a</sup> APO-Nifedipine XR [TX]	<sup>a</sup> Adalat Oros 60 [BN]

**SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS**

*Phenylalkylamine derivatives*

■ VERAPAMIL

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**verapamil hydrochloride 240 mg modified release tablet, 30**

1241H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.13	20.34	<sup>a</sup> Cordilox SR [GT]
			<sup>B</sup> 3.50	22.63	20.34	<sup>a</sup> Isoptin SR [GO]

**verapamil hydrochloride 40 mg tablet, 100**

1248Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.96	17.17	Anpec 40 [AF]

**verapamil hydrochloride 180 mg modified release tablet, 30**

2208F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.12	18.33	<sup>a</sup> Cordilox 180 SR [GT]
			<sup>B</sup> 3.50	20.62	18.33	<sup>a</sup> Isoptin 180 SR [GO]

**verapamil hydrochloride 80 mg tablet, 100**

1250T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.56	19.77	<sup>a</sup> Anpec 80 [AF]
			<sup>B</sup> 3.50	22.06	19.77	<sup>a</sup> Isoptin [GO]

*Benzothiazepine derivatives*

■ DILTIAZEM

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**diltiazem hydrochloride 240 mg modified release capsule, 30**

1313D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.18	21.39	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 1.90	22.08	21.39	<sup>a</sup> Cardizem CD [SW]	

**diltiazem hydrochloride 360 mg modified release capsule, 30**

8480H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.00	24.21	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 1.90	24.90	24.21	<sup>a</sup> Cardizem CD [SW]	

**diltiazem hydrochloride 180 mg modified release capsule, 30**

1312C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.81	19.02	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 1.90	19.71	19.02	<sup>a</sup> Cardizem CD [SW]	

**diltiazem hydrochloride 60 mg tablet, 90**

1335G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.15	18.36	<sup>a</sup> Diltiazem Actavis [ED]	<sup>a</sup> Diltiazem AN [EA]
						<sup>a</sup> Diltiazem Sandoz [SZ]	
			<sup>B</sup> 1.90	19.05	18.36	<sup>a</sup> Cardizem [SW]	<sup>a</sup> Vasocardol [AV]

**AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM**

**ACE INHIBITORS, PLAIN**

*ACE inhibitors, plain*

**CAPTOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**captopril 50 mg tablet, 90**

1149L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.65	21.86	<sup>a</sup> Captopril Sandoz [SZ]
			<sup>B</sup> 3.43	24.08	21.86	<sup>a</sup> Zedace [AF]
			<sup>B</sup> 3.90	24.55	21.86	<sup>a</sup> Capoten [RW]

**captopril 25 mg tablet, 90**

1148K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.94	17.15	<sup>a</sup> Captopril Sandoz [SZ]
			<sup>B</sup> 3.43	19.37	17.15	<sup>a</sup> Zedace [AF]
			<sup>B</sup> 4.67	20.61	17.15	<sup>a</sup> Capoten [RW]

**captopril 12.5 mg tablet, 90**

1147J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.44	15.65	<sup>a</sup> Captopril Sandoz [SZ]
			<sup>B</sup> 3.43	17.87	15.65	<sup>a</sup> Zedace [AF]

**CAPTOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Patients unable to take a solid dose form of an ACE inhibitor.

**captopril 5 mg/mL oral liquid, 95 mL**

8760C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	106.91	38.80	Capoten [RW]

**ENALAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**enalapril maleate 5 mg tablet, 30**

1370D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.96	14.17	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]
						<sup>a</sup> Enalapril Actavis [ED]	<sup>a</sup> Enalapril generichealth [GQ]
						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> Malean [RW]

**enalapril maleate 10 mg tablet, 30**

1368B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.18	15.39	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]
						<sup>a</sup> Enalapril Actavis [ED]	<sup>a</sup> Enalapril generichealth [GQ]
						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> Malean [RW]
			<sup>B</sup> 6.40	20.58	15.39	<sup>a</sup> Renitec [MK]	

**enalapril maleate 20 mg tablet, 30**

1369C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.01	16.22	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]
						<sup>a</sup> Enalapril Actavis [ED]	<sup>a</sup> Enalapril generichealth [GQ]
						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> Malean [RW]
						<sup>b</sup> 6.40	21.41

▪ **FOSINOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**fosinopril sodium 20 mg tablet, 30**

1183G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.80	19.01	<sup>a</sup> APO-Fosinopril [TX]	<sup>a</sup> Fosipril 20 [RW]
						<sup>a</sup> Monace 20 [AF]	

**fosinopril sodium 10 mg tablet, 30**

1182F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.58	16.79	<sup>a</sup> APO-Fosinopril [TX]	<sup>a</sup> Fosipril 10 [RW]
						<sup>a</sup> Monace 10 [AF]	

▪ **LISINOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**lisinopril 5 mg tablet, 30**

2456G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.25	14.46	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Auro-Lisinopril 5 [DO]
						<sup>a</sup> Chem mart Lisinopril [CH]	<sup>a</sup> Fibsol 5 [RW]
						<sup>a</sup> Lisinopril AN [EA]	<sup>a</sup> Lisinopril generichealth [GQ]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> Terry White Chemists Lisinopril [TW]
						<sup>a</sup> Zinopril 5 [AL]	
						<sup>b</sup> 3.30	16.55

**lisinopril 20 mg tablet, 30**

2458J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.17	16.38	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Auro-Lisinopril 20 [DO]
						<sup>a</sup> Chem mart Lisinopril [CH]	<sup>a</sup> Fibsol 20 [RW]
						<sup>a</sup> Lisinopril AN [EA]	<sup>a</sup> Lisinopril generichealth [GQ]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> Terry White Chemists Lisinopril [TW]
						<sup>a</sup> Zinopril 20 [AL]	
						<sup>b</sup> 3.30	18.47

**lisinopril 10 mg tablet, 30**

2457H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.33	15.54	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Auro-Lisinopril 10 [DO]
						<sup>a</sup> Chem mart Lisinopril [CH]	<sup>a</sup> Fibsol 10 [RW]
						<sup>a</sup> Lisinopril AN [EA]	<sup>a</sup> Lisinopril generichealth [GQ]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> Terry White Chemists Lisinopril [TW]
						<sup>a</sup> Zinopril 10 [AL]	
						<sup>b</sup> 3.30	17.63

▪ **PERINDOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

**perindopril arginine 2.5 mg tablet, 30**

9006B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer			
NP	1	5	..	12.63	13.84	<sup>a</sup> APO-Perindopril Arginine [TX]	<sup>a</sup> PREXUM 2.5 [RW]			
						<sup>b</sup> 4.95	17.58	13.84	<sup>a</sup> Coversyl 2.5mg [SE]	

**perindopril erbumine 2 mg tablet, 30**

3050M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.63	13.84	<sup>a</sup> APO-Perindopril [TX]	<sup>a</sup> Blooms the Chemist Perindopril [IB]
						<sup>a</sup> Chem mart Perindopril [CH]	<sup>a</sup> Idaprex 2 [SZ]
						<sup>a</sup> Indosyl Mono 2 [RW]	<sup>a</sup> Perindo [AF]

<sup>a</sup> Perindopril Actavis 2 [EA]    <sup>a</sup> Perindopril AN [EF]  
<sup>a</sup> Terry White Chemists  
 Perindopril [TW]

▪ **PERINDOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

**perindopril erbumine 4 mg tablet, 30**

3051N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.95	15.16	<sup>a</sup> APO-Perindopril [TX]	<sup>a</sup> Blooms the Chemist Perindopril [IB]
						<sup>a</sup> Chem mart Perindopril [CH]	<sup>a</sup> Idaprex 4 [SZ]
						<sup>a</sup> Indosyl Mono 4 [RW]	<sup>a</sup> Perindo [AF]
						<sup>a</sup> Perindopril Actavis 4 [ED]	<sup>a</sup> Perindopril AN [EF]
						<sup>a</sup> Perindopril generichealth [GQ]	<sup>a</sup> Terry White Chemists Perindopril [TW]

**perindopril arginine 5 mg tablet, 30**

9007C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.95	15.16	<sup>a</sup> APO-Perindopril Arginine [TX]	<sup>a</sup> PREXUM 5 [RW]
			<sup>B</sup> 4.95	18.90	15.16	<sup>a</sup> Coversyl 5mg [SE]	

▪ **PERINDOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

**perindopril arginine 10 mg tablet, 30**

9008D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.47	16.68	<sup>a</sup> APO-Perindopril Arginine [TX]	<sup>a</sup> PREXUM 10 [RW]
			<sup>B</sup> 4.95	20.42	16.68	<sup>a</sup> Coversyl 10mg [SE]	

**perindopril erbumine 8 mg tablet, 30**

8704D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.47	16.68	<sup>a</sup> APO-Perindopril [TX]	<sup>a</sup> Blooms the Chemist Perindopril [IB]
						<sup>a</sup> Chem mart Perindopril [CH]	<sup>a</sup> Idaprex 8 [SZ]
						<sup>a</sup> Indosyl Mono 8 [RW]	<sup>a</sup> Perindo [AF]
						<sup>a</sup> Perindopril Actavis 8 [ED]	<sup>a</sup> Perindopril AN [EF]
						<sup>a</sup> Perindopril generichealth [GQ]	<sup>a</sup> Terry White Chemists Perindopril [TW]

▪ **QUINAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**quinapril 10 mg tablet, 30**

1969P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.08	16.29	<sup>a</sup> Acquin Aspen 10 [RW]	<sup>a</sup> APO-Quinapril [TX]
						<sup>a</sup> Qpril 10 [AF]	
			<sup>B</sup> 4.20	19.28	16.29	<sup>a</sup> Accupril [PF]	

**quinapril 5 mg tablet, 30**

1968N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.22	15.43	<sup>a</sup> ACQUIN [RF]	<sup>a</sup> Acquin Aspen 5 [RW]
						<sup>a</sup> Qpril 5 [AF]	
			<sup>B</sup> 4.20	18.42	15.43	<sup>a</sup> Accupril [PF]	

**quinapril 20 mg tablet, 30**

1970Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.01	17.22	<sup>a</sup> ACQUIN [RF]	<sup>a</sup> Acquin Aspen 20 [RW]
						<sup>a</sup> APO-Quinapril [TX]	<sup>a</sup> Qpril 20 [AF]
						<sup>a</sup> Quinapril generichealth [GQ]	
			<sup>B</sup> 4.20	20.21	17.22	<sup>a</sup> Accupril [PF]	

▪ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

**ramipril 10 mg capsule, 30**

8470T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.39	15.60	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramace 10 mg [AV] <sup>a</sup> Ramipril generichealth [GQ] <sup>a</sup> Ramipril Winthrop [WA]  <sup>a</sup> Tritace 10 mg [SW] <sup>a</sup> Vascalace Caps 10 [DO]	<sup>a</sup> Chem mart Ramipril [CH] <sup>a</sup> Ramipril AN [EA] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> Terry White Chemists Ramipril [TW] <sup>a</sup> Tryzan Caps 10 [AF]

**ramipril 10 mg tablet, 30**

1316G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.39	15.60	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramipril AN [EA] <sup>a</sup> Ramipril Winthrop [WA]  <sup>a</sup> Tritace [SW] <sup>a</sup> Vascalace 10 [DO]	<sup>a</sup> Chem mart Ramipril [CH] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> Terry White Chemists Ramipril [TW] <sup>a</sup> Tryzan Tabs 10 [AF]

■ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

**ramipril 1.25 mg capsule, 30**

9120B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.11	13.32	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Terry White Chemists Ramipril [TW] <sup>a</sup> Vascalace Caps 1.25 [DO]	<sup>a</sup> Chem mart Ramipril [CH] <sup>a</sup> Tryzan Caps 1.25 [AF]

**ramipril 1.25 mg tablet, 30**

1944H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.11	13.32	<sup>a</sup> Ramace 1.25 mg [AV] <sup>a</sup> Ramipril Winthrop [WA] <sup>a</sup> Tryzan Tabs 1.25 [AF]	<sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> Tritace 1.25 mg [SW] <sup>a</sup> Vascalace 1.25 [DO]

■ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

**ramipril 2.5 mg tablet, 30**

1945J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.58	13.79	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramace 2.5 mg [AV] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> Terry White Chemists Ramipril [TW] <sup>a</sup> Tryzan Tabs 2.5 [AF]	<sup>a</sup> Chem mart Ramipril [CH] <sup>a</sup> Ramipril AN [EA] <sup>a</sup> Ramipril Winthrop [WA] <sup>a</sup> Tritace 2.5 mg [SW] <sup>a</sup> Vascalace 2.5 [DO]

**ramipril 2.5 mg capsule, 30**

9121C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.58	13.79	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramipril generichealth [GQ]  <sup>a</sup> Tryzan Caps 2.5 [AF]	<sup>a</sup> Chem mart Ramipril [CH] <sup>a</sup> Terry White Chemists Ramipril [TW] <sup>a</sup> Vascalace Caps 2.5 [DO]

■ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

**ramipril 5 mg tablet, 30**

1946K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.96	14.17	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramace 5 mg [AV] <sup>a</sup> Ramipril Sandoz [SZ]	<sup>a</sup> Chem mart Ramipril [CH] <sup>a</sup> Ramipril AN [EA] <sup>a</sup> Ramipril Winthrop [WA]

<sup>a</sup> Terry White Chemists Ramipril [TW]  
<sup>a</sup> Tryzan Tabs 5 [AF]      <sup>a</sup> Tritace 5 mg [SW]  
<sup>a</sup> Vascalace 5 [DO]

**ramipril 5 mg capsule, 30**

9122D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.96	14.17	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramipril generichealth [GQ] <sup>a</sup> Tryzan Caps 5 [AF]	<sup>a</sup> Chem mart Ramipril [CH] <sup>a</sup> Terry White Chemists Ramipril [TW] <sup>a</sup> Vascalace Caps 5 [DO]

**■ TRANDOLAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**trandolapril 4 mg capsule, 28**

8758Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	.. <sup>B</sup> 3.49	20.08 23.57	21.29 21.29	<sup>a</sup> Dolapril 4 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

**trandolapril 500 microgram capsule, 28**

2791X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	.. <sup>B</sup> 3.50	13.20 16.70	14.41 14.41	<sup>a</sup> Dolapril 0.5 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

**trandolapril 2 mg capsule, 28**

2793B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	.. <sup>B</sup> 3.50	15.87 19.37	17.08 17.08	<sup>a</sup> Dolapril 2 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

**trandolapril 1 mg capsule, 28**

2792Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	.. <sup>B</sup> 3.50	15.06 18.56	16.27 16.27	<sup>a</sup> Dolapril 1 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

**ACE INHIBITORS, COMBINATIONS**

*ACE inhibitors and diuretics*

**■ ENALAPRIL + HYDROCHLOROTHIAZIDE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30**

8477E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	.. <sup>B</sup> 6.99	16.46 23.45	17.67 17.67	<sup>a</sup> Enalapril/HCT Sandoz [SZ] <sup>a</sup> Renitec Plus 20/6 [MK]

**■ FOSINOPRIL + HYDROCHLOROTHIAZIDE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8401E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.49	20.70	<sup>a</sup> APO-Fosinopril HCTZ 20/12.5 [TX] <sup>a</sup> Fosinopril/HCT Actavis 20/12.5 [EA]	<sup>a</sup> Fosetic 20/12.5 [ZP]

**■ PERINDOPRIL + INDAPAMIDE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

2190G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	13.07	14.28	<sup>a</sup> PREXUM Combi LD 2.5/0.625 [RW]
			<sup>B</sup> 4.94	18.01	14.28	<sup>a</sup> Coversyl Plus LD 2.5mg/0.625mg [SE]

**■ PERINDOPRIL + INDAPAMIDE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

8449Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.83	16.04	<sup>a</sup> Chem mart Perindopril/ Indapamide 4/1.25 [CH]	<sup>a</sup> GenRx Perindopril/ Indapamide 4/1.25 [GX]
						<sup>a</sup> Idaprex Combi 4/1.25 [SZ]	<sup>a</sup> Indosyl Combi 4/1.25 [RW]
						<sup>a</sup> Perindopril and Indapamide AN 4/1.25 [EF]	<sup>a</sup> Perindopril Combi Actavis 4/1.25 [ED]
						<sup>a</sup> Perindopril/ Indapamide GH 4/1.25 [GQ]	<sup>a</sup> Terry White Chemists Perindopril/ Indapamide 4/1.25 [TW]
			<sup>B</sup> 2.94	17.77	16.04	<sup>a</sup> Perindo Combi 4/1.25 [AF]	

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

2845R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.83	16.04	<sup>a</sup> Prexum Combi 5/1.25 [RW]
			<sup>B</sup> 4.95	19.78	16.04	<sup>a</sup> Coversyl Plus 5mg/1.25mg [SE]

**■ QUINAPRIL + HYDROCHLOROTHIAZIDE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8590D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.85	19.06	Accuretic 20/12.5mg [PF]

**quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8589C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.92	18.13	Accuretic 10/12.5mg [PF]

*ACE inhibitors and calcium channel blockers*

**■ LERCANIDIPINE + ENALAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28**

9145H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.85	18.06	Zan-Extra 10/20 [GO]

**lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28**

9144G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.07	17.28	Zan-Extra 10/10 [GO]

**■ PERINDOPRIL + AMLODIPINE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Stable coronary heart disease

**Clinical criteria:**

- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

**perindopril arginine 10 mg + amlodipine 10 mg tablet, 30**

9349C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.05	18.26	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 10/10 [TX]	<sup>a</sup> Reaptan 10/10 [RW]
			<sup>B</sup> 4.95	22.00	18.26	<sup>a</sup> Coveram 10/10 [SE]	

**perindopril arginine 10 mg + amlodipine 5 mg tablet, 30**

9348B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.36	17.57	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 10/5 [TX]	<sup>a</sup> Reaptan 10/5 [RW]
			<sup>B</sup> 4.94	21.30	17.57	<sup>a</sup> Coveram 10/5 [SE]	

**perindopril arginine 5 mg + amlodipine 5 mg tablet, 30**

9346X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.84	16.05	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 5/5 [TX]	<sup>a</sup> Reaptan 5/5 [RW]
			<sup>B</sup> 4.95	19.79	16.05	<sup>a</sup> Coveram 5/5 [SE]	

**perindopril arginine 5 mg + amlodipine 10 mg tablet, 30**

9347Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.53	16.74	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 5/10 [TX]	<sup>a</sup> Reaptan 5/10 [RW]
			<sup>B</sup> 4.95	20.48	16.74	<sup>a</sup> Coveram 5/10 [SE]	

**■ RAMIPRIL + FELODIPINE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30**

2626F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.39	16.60	Triasyn 2.5/2.5 [SW]

**ramipril 5 mg + felodipine 5 mg modified release tablet, 30**

2629J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.99	18.20	Triasyn 5.0/5.0 [SW]

**■ TRANDOLAPRIL + VERAPAMIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

**trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28**

2857J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.58	28.79	Tarka 4/240 [GO]

**trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28**

9387C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	21.51	22.72	Tarka 2/180 [GO]

**ANGIOTENSIN II ANTAGONISTS, PLAIN**

*Angiotensin II antagonists, plain*

■ **CANDESARTAN**

**candesartan cilexetil 16 mg tablet, 30**

8297Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.22	16.43	<sup>a</sup> Adesan [AF] <sup>a</sup> Auro-Candesartan 16 [DO] <sup>a</sup> CANDESAN [RF] <sup>a</sup> Candesartan Aspen 16 [RW] <sup>a</sup> Candesartan Sandoz [SZ] <sup>a</sup> Terry White Chemists Candesartan [TW]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> Blooms the Chemist Candesartan [IB] <sup>a</sup> Candesartan AN [EA] <sup>a</sup> Candesartan GH [GQ] <sup>a</sup> Chem mart Candesartan [CH]
			<sup>b</sup> 4.00	19.22	16.43	<sup>a</sup> Atacand [AP]	

**candesartan cilexetil 4 mg tablet, 30**

8295N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.55	12.76	<sup>a</sup> Adesan [AF] <sup>a</sup> Auro-Candesartan 4 [DO] <sup>a</sup> CANDESAN [RF] <sup>a</sup> Candesartan Aspen 4 [RW] <sup>a</sup> Candesartan Sandoz [SZ] <sup>a</sup> Terry White Chemists Candesartan [TW]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> Blooms the Chemist Candesartan [IB] <sup>a</sup> Candesartan AN [EA] <sup>a</sup> Candesartan GH [GQ] <sup>a</sup> Chem mart Candesartan [CH]
			<sup>b</sup> 4.00	15.55	12.76	<sup>a</sup> Atacand [AP]	

**candesartan cilexetil 32 mg tablet, 30**

8889W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.08	17.29	<sup>a</sup> Adesan [AF] <sup>a</sup> Auro-Candesartan 32 [DO] <sup>a</sup> CANDESAN [RF] <sup>a</sup> Candesartan Aspen 32 [RW] <sup>a</sup> Candesartan Sandoz [SZ] <sup>a</sup> Terry White Chemists Candesartan [TW]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> Blooms the Chemist Candesartan [IB] <sup>a</sup> Candesartan AN [EA] <sup>a</sup> Candesartan GH [GQ] <sup>a</sup> Chem mart Candesartan [CH]
			<sup>b</sup> 6.63	22.71	17.29	<sup>a</sup> Atacand [AP]	

**candesartan cilexetil 8 mg tablet, 30**

8296P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.48	13.69	<sup>a</sup> Adesan [AF] <sup>a</sup> Auro-Candesartan 8 [DO] <sup>a</sup> CANDESAN [RF] <sup>a</sup> Candesartan Aspen 8 [RW] <sup>a</sup> Chem mart Candesartan [CH]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> Blooms the Chemist Candesartan [IB] <sup>a</sup> Candesartan AN [EA] <sup>a</sup> Candesartan Sandoz [SZ] <sup>a</sup> Terry White Chemists Candesartan [TW]
			<sup>b</sup> 4.00	16.48	13.69	<sup>a</sup> Atacand [AP]	

▪ EPROSARTAN

eprosartan 600 mg tablet, 28

8447N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	T3.50	30.08	27.79	Teveten [GO]

eprosartan 400 mg tablet, 28

8397Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	T7.00	*30.45	24.66	Teveten [GO]

▪ EPROSARTAN

**Authority required**

Adverse effects occurring with all of the base-priced drugs

**Authority required**

Drug interactions occurring with all of the base-priced drugs

**Authority required**

Drug interactions expected to occur with all of the base-priced drugs

**Authority required**

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

eprosartan 600 mg tablet, 28

5491B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	30.08	31.29	Teveten [GO]

eprosartan 400 mg tablet, 28

8951D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*30.45	31.66	Teveten [GO]

▪ IRBESARTAN

irbesartan 150 mg tablet, 30

8247C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.93	14.14	<sup>a</sup> Abisart [AF] <sup>a</sup> Blooms the Chemist Irbesartan [IB] <sup>a</sup> Irbesartan Actavis 150 [ED] <sup>a</sup> Irbesartan AN [EA] <sup>a</sup> Irbesartan RBX [RA] <sup>a</sup> Irprestan 150 [ZP]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Chem mart Irbesartan [CH] <sup>a</sup> Irbesartan AMNEAL [EF] <sup>a</sup> Irbesartan GH [GQ] <sup>a</sup> Irbesartan Sandoz [SZ] <sup>a</sup> Terry White Chemists Irbesartan [TW]
			<sup>B</sup> 1.90	14.83	14.14	<sup>a</sup> Avapro [AV]	<sup>a</sup> Karvea [SW]

irbesartan 75 mg tablet, 30

8246B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.38	13.59	<sup>a</sup> Abisart [AF] <sup>a</sup> Blooms the Chemist Irbesartan [IB] <sup>a</sup> Irbesartan Actavis 75 [ED] <sup>a</sup> Irbesartan AN [EA] <sup>a</sup> Irbesartan Sandoz [SZ] <sup>a</sup> Terry White Chemists Irbesartan [TW]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Chem mart Irbesartan [CH] <sup>a</sup> Irbesartan AMNEAL [EF] <sup>a</sup> Irbesartan GH [GQ] <sup>a</sup> Irprestan 75 [ZP]
			<sup>B</sup> 1.90	14.28	13.59	<sup>a</sup> Avapro [AV]	<sup>a</sup> Karvea [SW]

irbesartan 300 mg tablet, 30

8248D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.78	15.99	<sup>a</sup> Abisart [AF] <sup>a</sup> Blooms the Chemist Irbesartan [IB] <sup>a</sup> Irbesartan Actavis 300 [ED] <sup>a</sup> Irbesartan AN [EA] <sup>a</sup> Irbesartan RBX [RA] <sup>a</sup> Irprestan 300 [ZP]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Chem mart Irbesartan [CH] <sup>a</sup> Irbesartan AMNEAL [EF] <sup>a</sup> Irbesartan GH [GQ] <sup>a</sup> Irbesartan Sandoz [SZ] <sup>a</sup> Terry White Chemists Irbesartan [TW]
			<sup>B</sup> 1.90	16.68	15.99	<sup>a</sup> Avapro [AV]	<sup>a</sup> Karvea [SW]

■ **LOSARTAN**

**losartan potassium 25 mg tablet, 30**

5452Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.56	17.77	Cozavan [AF]

**losartan potassium 50 mg tablet, 30**

8203R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*26.73	27.94	Cozavan [AF]

■ **OLMESARTAN MEDOXOMIL**

**olmesartan medoxomil 40 mg tablet, 30**

2148C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	28.04	29.25	<sup>a</sup> APO-Olmesartan [TX] <sup>a</sup> Olmesartan AN [EA] <sup>a</sup> Olmesartan Sandoz [SZ]	<sup>a</sup> OLMERTAN [RW] <sup>a</sup> Olmesartan - MYL [AF] <sup>a</sup> Pharmacor Olmesartan 40 [CR]
			<sup>b</sup> 3.50	31.54	29.25	<sup>a</sup> Olmetec [MK]	

**olmesartan medoxomil 20 mg tablet, 30**

2147B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.08	20.29	<sup>a</sup> APO-Olmesartan [TX] <sup>a</sup> Olmesartan AN [EA] <sup>a</sup> Olmesartan Sandoz [SZ]	<sup>a</sup> OLMERTAN [RW] <sup>a</sup> Olmesartan - MYL [AF] <sup>a</sup> Pharmacor Olmesartan 20 [CR]
			<sup>b</sup> 3.50	22.58	20.29	<sup>a</sup> Olmetec [MK]	

■ **TELMISARTAN**

**telmisartan 40 mg tablet, 28**

8355R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.18	14.39	<sup>a</sup> APO-Telmisartan [TX] <sup>a</sup> Pharmacor Telmisartan 40 [CR] <sup>a</sup> Telmisartan-DRLA [RZ] <sup>a</sup> Telmisartan Sandoz [SZ]	<sup>a</sup> Mizart [AF] <sup>a</sup> Telmisartan AN [EA] <sup>a</sup> Telmisartan GH [GQ] <sup>a</sup> Teltartan [RW]
			<sup>b</sup> 2.68	15.86	14.39	<sup>a</sup> Micardis [BY]	

**telmisartan 80 mg tablet, 28**

8356T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.12	18.33	<sup>a</sup> APO-Telmisartan [TX] <sup>a</sup> Pharmacor Telmisartan 80 [CR] <sup>a</sup> Telmisartan-DRLA [RZ] <sup>a</sup> Telmisartan Sandoz [SZ]	<sup>a</sup> Mizart [AF] <sup>a</sup> Telmisartan AN [EA] <sup>a</sup> Telmisartan GH [GQ] <sup>a</sup> Teltartan [RW]
			<sup>b</sup> 2.69	19.81	18.33	<sup>a</sup> Micardis [BY]	

■ **VALSARTAN**

**valsartan 80 mg tablet, 28**

9369D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.99	21.20	<sup>a</sup> APO-Valsartan [TX] <sup>a</sup> Diovan [NV]	<sup>a</sup> Dilart [AF]

**valsartan 160 mg tablet, 28**

9370E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.52	23.73	<sup>a</sup> APO-Valsartan [TX] <sup>a</sup> Diovan [NV]	<sup>a</sup> Dilart [AF]

**valsartan 40 mg tablet, 28**

9368C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.20	18.41	<sup>a</sup> APO-Valsartan [TX] <sup>a</sup> Diovan [NV]	<sup>a</sup> Dilart [AF]

■ **VALSARTAN**

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

**valsartan 320 mg tablet, 28**

9371F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.74	26.95	<sup>a</sup> APO-Valsartan [TX] <sup>a</sup> Diovan [NV]	<sup>a</sup> Dilart [AF]

**ANGIOTENSIN II ANTAGONISTS, COMBINATIONS**

*Angiotensin II antagonists and diuretics*

■ **CANDESARTAN + HYDROCHLOROTHIAZIDE**

Restricted benefit

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30**

9314F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.27	17.48	<sup>a</sup> Adesan HCT 32/12.5 [AF] <sup>a</sup> Asartan HCT 32/12.5 [DO] <sup>a</sup> CANDESAN COMBI 32/12.5 [RF] <sup>a</sup> Candesartan HCT GH 32/12.5 [GQ] <sup>a</sup> Candesartan HCTZ AN 32/12.5 [EA] <sup>a</sup> Terry White Chemists Candesartan HCTZ 32/12.5 [TW]	<sup>a</sup> APO-Candesartan HCTZ 32/12.5 [TX] <sup>a</sup> Blooms the Chemist Candesartan HCTZ 32/12.5 [IB] <sup>a</sup> Candesartan Combi Aspen 32/12.5 [RW] <sup>a</sup> Candesartan/HCT Sandoz [SZ] <sup>a</sup> Chem mart Candesartan HCTZ 32/12.5 [CH]
			<sup>B</sup> 9.25	25.52	17.48	<sup>a</sup> Atacand Plus 32/12.5 [AP]	

**candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8504N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.52	16.73	<sup>a</sup> Adesan HCT 16/12.5 [AF] <sup>a</sup> Asartan HCT 16/12.5 [DO] <sup>a</sup> CANDESAN COMBI 16/12.5 [RF] <sup>a</sup> Candesartan HCT GH 16/12.5 [GQ] <sup>a</sup> Candesartan HCTZ AN 16/12.5 [EA] <sup>a</sup> Terry White Chemists Candesartan HCTZ 16/12.5 [TW]	<sup>a</sup> APO-Candesartan HCTZ 16/12.5 [TX] <sup>a</sup> Blooms the Chemist Candesartan HCTZ 16/12.5 [IB] <sup>a</sup> Candesartan Combi Aspen 16/12.5 [RW] <sup>a</sup> Candesartan/HCT Sandoz [SZ] <sup>a</sup> Chem mart Candesartan HCTZ 16/12.5 [CH]
			<sup>B</sup> 4.00	19.52	16.73	<sup>a</sup> Atacand Plus 16/12.5 [AP]	

**candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30**

9315G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.10	18.31	<sup>a</sup> Adesan HCT 32/25 [AF] <sup>a</sup> Asartan HCT 32/25 [DO] <sup>a</sup> CANDESAN COMBI 32/25 [RF] <sup>a</sup> Candesartan HCT GH 32/25 [GQ] <sup>a</sup> Candesartan HCTZ AN 32/25 [EA] <sup>a</sup> Terry White Chemists Candesartan HCTZ 32/25 [TW]	<sup>a</sup> APO-Candesartan HCTZ 32/25 [TX] <sup>a</sup> Blooms the Chemist Candesartan HCTZ 32/25 [IB] <sup>a</sup> Candesartan Combi Aspen 32/25 [RW] <sup>a</sup> Candesartan/HCT Sandoz [SZ] <sup>a</sup> Chem mart Candesartan HCTZ 32/25 [CH]
			<sup>B</sup> 7.75	24.85	18.31	<sup>a</sup> Atacand Plus 32/25 [AP]	

■ **EPROSARTAN + HYDROCHLOROTHIAZIDE**

Restricted benefit

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28**

8624X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	28.30	29.51	Teveten Plus 600/12.5 [GO]

▪ **IRBESARTAN + HYDROCHLOROTHIAZIDE**

Restricted benefit

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8405J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.96	16.17	<sup>a</sup> Abisart HCT 300/12.5 [AF]	<sup>a</sup> APO-Irbesartan HCTZ [TX]
						<sup>a</sup> Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB]	<sup>a</sup> Chem mart Irbesartan HCTZ [CH]
						<sup>a</sup> Irbesartan HCT Actavis 300/12.5 [ED]	<sup>a</sup> Irbesartan HCT GH 300/12.5 [GQ]
						<sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> Irbesartan HCTZ AMNEAL [EF]
						<sup>a</sup> Irbesartan HCTZ AN 300/12.5 [EA]	<sup>a</sup> KSART HCT 300/12.5 [RW]
						<sup>a</sup> Terry White Chemists Irbesartan HCTZ [TW]	
			<sup>B</sup> 1.90	16.86	16.17	<sup>a</sup> Avapro HCT 300/12.5 [AV]	<sup>a</sup> Karvezide 300/12.5 [SW]

**irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30**

2136K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.30	16.51	<sup>a</sup> Abisart HCT 300/25 [AF]	<sup>a</sup> APO-Irbesartan HCTZ [TX]
						<sup>a</sup> Blooms the Chemist Irbesartan HCTZ 300/25 [IB]	<sup>a</sup> Chem mart Irbesartan HCTZ [CH]
						<sup>a</sup> Irbesartan HCT Actavis 300/25 [ED]	<sup>a</sup> Irbesartan HCT GH 300/25 [GQ]
						<sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> Irbesartan HCTZ AMNEAL [EF]
						<sup>a</sup> Irbesartan HCTZ AN 300/25 [EA]	<sup>a</sup> Irbesartan/HCTZ RBX 300/25 [RA]
						<sup>a</sup> KSART HCT 300/25 [RW]	<sup>a</sup> Terry White Chemists Irbesartan HCTZ [TW]
			<sup>B</sup> 1.90	17.20	16.51	<sup>a</sup> Avapro HCT 300/25 [AV]	<sup>a</sup> Karvezide 300/25 [SW]

**irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8404H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.20	14.41	<sup>a</sup> Abisart HCT 150/12.5 [AF]	<sup>a</sup> APO-Irbesartan HCTZ [TX]
						<sup>a</sup> Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB]	<sup>a</sup> Chem mart Irbesartan HCTZ [CH]
						<sup>a</sup> Irbesartan HCT Actavis 150/12.5 [ED]	<sup>a</sup> Irbesartan HCT GH 150/12.5 [GQ]
						<sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> Irbesartan HCTZ AMNEAL [EF]
						<sup>a</sup> Irbesartan HCTZ AN 150/12.5 [EA]	<sup>a</sup> Irbesartan/HCTZ RBX 150/12.5 [RA]
						<sup>a</sup> KSART HCT 150/12.5 [RW]	<sup>a</sup> Terry White Chemists Irbesartan HCTZ [TW]
			<sup>B</sup> 1.90	15.10	14.41	<sup>a</sup> Avapro HCT 150/12.5 [AV]	<sup>a</sup> Karvezide 150/12.5 [SW]

▪ **OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE**

Restricted benefit

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30**

2170F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	31.12	32.33	<sup>a</sup> APO-Olmesartan/HCTZ 40/25 [TX]	<sup>a</sup> OLMERTAN COMBI 40/25 [RW]
						<sup>a</sup> Olmesartan HCT AN 40/25 [EA]	<sup>a</sup> Olmesartan HCT - MYL 40/25 [AF]
						<sup>a</sup> Olmesartan/HCT Sandoz [SZ]	<sup>a</sup> Olmetec Plus [MK]

**olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30**

2166B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.58	30.79	<sup>a</sup> APO-Olmesartan/HCTZ 40/12.5 [TX]	<sup>a</sup> OLMERTAN COMBI 40/12.5 [RW]
						<sup>a</sup> Olmesartan HCT AN 40/12.5 [EA]	<sup>a</sup> Olmesartan HCT - MYL 40/12.5 [AF]
						<sup>a</sup> Olmesartan/HCT Sandoz [SZ]	<sup>a</sup> Olmetec Plus [MK]

**olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

2161R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.63	21.84	<sup>a</sup> APO-Olmesartan/HCTZ 20/12.5 [TX]	<sup>a</sup> OLMERTAN COMBI 20/12.5 [RW]
						<sup>a</sup> Olmesartan HCT AN 20/12.5 [EA]	<sup>a</sup> Olmesartan HCT - MYL 20/12.5 [AF]
						<sup>a</sup> Olmesartan/HCT Sandoz [SZ]	<sup>a</sup> Olmetec Plus [MK]

**■ TELMISARTAN + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28**

8622T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.37	14.58	<sup>a</sup> APO-Telmisartan HCTZ 40/12.5 [TX]	<sup>a</sup> Mizart HCT 40/12.5 mg [AF]
						<sup>a</sup> Pritor Plus 40/12.5 mg [FI]	<sup>a</sup> Telmisartan HCT GH 40/12.5 [GQ]
						<sup>a</sup> Telmisartan/HCT Sandoz [SZ]	<sup>a</sup> Telmisartan HCTZ AN 40/12.5 [EA]
						<sup>a</sup> Teltartan HCT 40/12.5 [RW]	
			<sup>b</sup> 2.69	16.06	14.58	<sup>a</sup> Micardis Plus 40/12.5 mg [BY]	

**telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

8623W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.78	17.99	<sup>a</sup> APO-Telmisartan HCTZ 80/12.5 [TX]	<sup>a</sup> Mizart HCT 80/12.5 mg [AF]
						<sup>a</sup> Pritor Plus 80/12.5 mg [FI]	<sup>a</sup> Telmisartan HCT GH 80/12.5 [GQ]
						<sup>a</sup> Telmisartan/HCT Sandoz [SZ]	<sup>a</sup> Telmisartan HCTZ AN 80/12.5 [EA]
						<sup>a</sup> Teltartan HCT 80/12.5 [RW]	
			<sup>b</sup> 2.69	19.47	17.99	<sup>a</sup> Micardis Plus 80/12.5 mg [BY]	

**telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28**

9381R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.28	18.49	<sup>a</sup> APO-Telmisartan HCTZ 80/25 [TX]	<sup>a</sup> Mizart HCT 80/25 mg [AF]
						<sup>a</sup> Pritor Plus 80/25 mg [FI]	<sup>a</sup> Telmisartan HCT GH 80/25 [GQ]
						<sup>a</sup> Telmisartan/HCT Sandoz [SZ]	<sup>a</sup> Telmisartan HCTZ AN 80/25 [EA]
						<sup>a</sup> Teltartan HCT 80/25 [RW]	
			<sup>b</sup> 2.69	19.97	18.49	<sup>a</sup> Micardis Plus 80/25 mg [BY]	

**■ VALSARTAN + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**

- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

9372G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.51	22.72	<sup>a</sup> APO-Valsartan HCTZ 80/12.5 [TX] <sup>a</sup> Dilart HCT 80/12.5 [AF]	<sup>a</sup> Co-Diovan 80/12.5 [NV]

**valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

9374J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.55	26.76	<sup>a</sup> APO-Valsartan HCTZ 160/25 [TX] <sup>a</sup> Dilart HCT 160/25 [AF]	<sup>a</sup> Co-Diovan 160/25 [NV]

**valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

9373H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.04	25.25	<sup>a</sup> APO-Valsartan HCTZ 160/12.5 [TX] <sup>a</sup> Dilart HCT 160/12.5 [AF]	<sup>a</sup> Co-Diovan 160/12.5 [NV]

**▪ VALSARTAN + HYDROCHLOROTHIAZIDE**

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

9482C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.78	29.99	<sup>a</sup> APO-Valsartan HCTZ 320/25 [TX] <sup>a</sup> Dilart HCT 320/25 [AF]	<sup>a</sup> Co-Diovan 320/25 [NV]

**valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28**

9481B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.26	28.47	<sup>a</sup> APO-Valsartan HCTZ 320/12.5 [TX] <sup>a</sup> Dilart HCT 320/12.5 [AF]	<sup>a</sup> Co-Diovan 320/12.5 [NV]

*Angiotensin II antagonists and calcium channel blockers*

**▪ AMLODIPINE + VALSARTAN**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**amlodipine 10 mg + valsartan 160 mg tablet, 28**

9377M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.99	25.20	Exforge 10/160 [NV]

**amlodipine 5 mg + valsartan 80 mg tablet, 28**

9375K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.82	22.03	<sup>a</sup> Exforge 5/80 [NV]	<sup>a</sup> Valsartan/Amlodipine Sandoz 80/5 [NM]

**amlodipine 5 mg + valsartan 320 mg tablet, 28**

5459H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.57	27.78	Exforge 5/320 [NV]

**amlodipine 10 mg + valsartan 320 mg tablet, 28**

5460J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.22	28.43	Exforge 10/320 [NV]

**amlodipine 5 mg + valsartan 160 mg tablet, 28**

9376L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.35	24.56	Exforge 5/160 [NV]

**■ OLMESARTAN MEDOXOMIL + AMLODIPINE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30**

5292M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.97	21.18	<sup>a</sup> Olmesartan/Amlodipine - MYL 20/5 [AF]	<sup>a</sup> Sevikar 20/5 [MK]

**olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30**

5294P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.62	30.83	<sup>a</sup> Olmesartan/Amlodipine - MYL 40/10 [AF]	<sup>a</sup> Sevikar 40/10 [MK]

**olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30**

5293N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.93	30.14	<sup>a</sup> Olmesartan/Amlodipine - MYL 40/5 [AF]	<sup>a</sup> Sevikar 40/5 [MK]

**■ TELMISARTAN + AMLODIPINE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**telmisartan 40 mg + amlodipine 10 mg tablet, 28**

8979N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.65	15.86	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>b</sup> 2.69	17.34	15.86	<sup>a</sup> Twynsta [BY]

**telmisartan 80 mg + amlodipine 5 mg tablet, 28**

8980P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.95	19.16	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>b</sup> 2.69	20.64	19.16	<sup>a</sup> Twynsta [BY]

**telmisartan 40 mg + amlodipine 5 mg tablet, 28**

8978M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.00	15.21	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>b</sup> 2.69	16.69	15.21	<sup>a</sup> Twynsta [BY]

**telmisartan 80 mg + amlodipine 10 mg tablet, 28**

8981Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.59	19.80	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>b</sup> 2.69	21.28	19.80	<sup>a</sup> Twynsta [BY]

*Angiotensin II antagonists, other combinations*

**■ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

5289J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	30.25	31.46	Exforge HCT 10/320/25 [NV]

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

5286F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.38	27.59	Exforge HCT 5/160/25 [NV]

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

5287G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	25.51	26.72	Exforge HCT 10/160/12.5 [NV]

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

5285E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.86	26.07	<sup>a</sup> Exforge HCT 5/160/12.5 [NV]	<sup>a</sup> Valsartan/Amlodipine/HCT Sandoz 160/5/12.5 [NM]

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

5288H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.02	28.23	Exforge HCT 10/160/25 [NV]

**■ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30**

2864R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.60	33.81	Sevikar HCT 40/5/25 [MK]

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30**

2953K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	33.29	34.50	Sevikar HCT 40/10/25 [MK]

**olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

10005N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	21.81	23.02	Sevikar HCT 20/5/12.5 [MK]

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

2880N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	30.77	31.98	Sevikar HCT 40/5/12.5 [MK]

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

2836G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	31.45	32.66	Sevikar HCT 40/10/12.5 [MK]

**■ SACUBITRIL + VALSARTAN**

**Note Continuing Therapy Only:**

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

**Note Special Pricing Arrangements apply.**

**Authority required (STREAMLINED)**

**6915**

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

**sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56**

11122J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	202.22	38.80	Entresto [NV]

**sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56**

11123K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	202.22	38.80	Entresto [NV]

**sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56**

11131W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	202.22	38.80	Entresto [NV]

**LIPID MODIFYING AGENTS**

**LIPID MODIFYING AGENTS, PLAIN**

*HMG CoA reductase inhibitors*

**ATORVASTATIN**

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**atorvastatin 40 mg tablet, 30**

8215J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.26	15.47	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin GH [GQ] <sup>a</sup> Atorvastatin SCP 40 [RZ] <sup>a</sup> Blooms the Chemist Atorvastatin [IB] <sup>a</sup> Lipitor [PF] <sup>a</sup> Pharmacor Atorvastatin [CR]  <sup>a</sup> Torvastat 40 [RW]	<sup>a</sup> Atorvastatin Amneal [EF] <sup>a</sup> Atorvastatin Sandoz [SZ] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> Chem mart Atorvastatin [CH]  <sup>a</sup> Lorstat 40 [AF] <sup>a</sup> Terry White Chemists Atorvastatin [TW] <sup>a</sup> Trovas [RA]

**atorvastatin 10 mg tablet, 30**

8213G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.62	13.83	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin GH [GQ] <sup>a</sup> Atorvastatin SCP 10 [RZ] <sup>a</sup> Blooms the Chemist Atorvastatin [IB] <sup>a</sup> Lipitor [PF] <sup>a</sup> Pharmacor Atorvastatin [CR]  <sup>a</sup> Torvastat 10 [RW]	<sup>a</sup> Atorvastatin Amneal [EF] <sup>a</sup> Atorvastatin Sandoz [SZ] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> Chem mart Atorvastatin [CH]  <sup>a</sup> Lorstat 10 [AF] <sup>a</sup> Terry White Chemists Atorvastatin [TW] <sup>a</sup> Trovas [RA]

**atorvastatin 80 mg tablet, 30**

8521L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.63	16.84	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin GH [GQ] <sup>a</sup> Atorvastatin SCP 80 [RZ] <sup>a</sup> Blooms the Chemist Atorvastatin [IB] <sup>a</sup> Lipitor [PF] <sup>a</sup> Pharmacor Atorvastatin [CR]  <sup>a</sup> Torvastat 80 [RW]	<sup>a</sup> Atorvastatin Amneal [EF] <sup>a</sup> Atorvastatin Sandoz [SZ] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> Chem mart Atorvastatin [CH]  <sup>a</sup> Lorstat 80 [AF] <sup>a</sup> Terry White Chemists Atorvastatin [TW] <sup>a</sup> Trovas [RA]

**atorvastatin 20 mg tablet, 30**

8214H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.35	14.56	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin GH [GQ] <sup>a</sup> Atorvastatin SCP 20 [RZ] <sup>a</sup> Blooms the Chemist Atorvastatin [IB] <sup>a</sup> Lipitor [PF] <sup>a</sup> Pharmacor Atorvastatin [CR]  <sup>a</sup> Torvastat 20 [RW]	<sup>a</sup> Atorvastatin Amneal [EF] <sup>a</sup> Atorvastatin Sandoz [SZ] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> Chem mart Atorvastatin [CH]  <sup>a</sup> Lorstat 20 [AF] <sup>a</sup> Terry White Chemists Atorvastatin [TW] <sup>a</sup> Trovas [RA]

▪ **ATORVASTATIN**

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**atorvastatin 40 mg tablet, 30**

9232X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.26	15.47	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin GH [GQ] <sup>a</sup> Atorvastatin SCP 40 [RZ] <sup>a</sup> Blooms the Chemist Atorvastatin [IB] <sup>a</sup> Lipitor [PF] <sup>a</sup> Pharmacor Atorvastatin [CR]  <sup>a</sup> Torvastat 40 [RW]	<sup>a</sup> Atorvastatin Amneal [EF] <sup>a</sup> Atorvastatin Sandoz [SZ] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> Chem mart Atorvastatin [CH]  <sup>a</sup> Lorstat 40 [AF] <sup>a</sup> Terry White Chemists Atorvastatin [TW] <sup>a</sup> Trovas [RA]

**atorvastatin 10 mg tablet, 30**

9230T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.62	13.83	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin GH [GQ] <sup>a</sup> Atorvastatin SCP 10 [RZ] <sup>a</sup> Blooms the Chemist Atorvastatin [IB] <sup>a</sup> Lipitor [PF] <sup>a</sup> Pharmacor Atorvastatin [CR]  <sup>a</sup> Torvastat 10 [RW]	<sup>a</sup> Atorvastatin Amneal [EF] <sup>a</sup> Atorvastatin Sandoz [SZ] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> Chem mart Atorvastatin [CH]  <sup>a</sup> Lorstat 10 [AF] <sup>a</sup> Terry White Chemists Atorvastatin [TW] <sup>a</sup> Trovas [RA]

**atorvastatin 80 mg tablet, 30**

9233Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	15.63	16.84	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin GH [GQ] <sup>a</sup> Atorvastatin SCP 80 [RZ] <sup>a</sup> Blooms the Chemist Atorvastatin [IB] <sup>a</sup> Lipitor [PF] <sup>a</sup> Pharmacor Atorvastatin [CR]  <sup>a</sup> Torvastat 80 [RW]	<sup>a</sup> Atorvastatin Amneal [EF] <sup>a</sup> Atorvastatin Sandoz [SZ] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> Chem mart Atorvastatin [CH]  <sup>a</sup> Lorstat 80 [AF] <sup>a</sup> Terry White Chemists Atorvastatin [TW] <sup>a</sup> Trovas [RA]

**atorvastatin 20 mg tablet, 30**

9231W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.35	14.56	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin GH [GQ] <sup>a</sup> Atorvastatin SCP 20 [RZ] <sup>a</sup> Blooms the Chemist Atorvastatin [IB] <sup>a</sup> Lipitor [PF] <sup>a</sup> Pharmacor Atorvastatin [CR]  <sup>a</sup> Torvastat 20 [RW]	<sup>a</sup> Atorvastatin Amneal [EF] <sup>a</sup> Atorvastatin Sandoz [SZ] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> Chem mart Atorvastatin [CH]  <sup>a</sup> Lorstat 20 [AF] <sup>a</sup> Terry White Chemists Atorvastatin [TW] <sup>a</sup> Trovas [RA]

▪ **FLUVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**fluvastatin 80 mg modified release tablet, 28**

2863Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	45.59	38.80	Lescol XL [NV]

▪ **FLUVASTATIN**

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**fluvastatin 80 mg modified release tablet, 28**

9236D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	45.59	38.80	Lescol XL [NV]

▪ **PRAVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**pravastatin sodium 20 mg tablet, 30**

2834E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.53	14.74	<sup>a</sup> APO-Pravastatin [TX] <sup>a</sup> Chem mart Pravastatin [CH] <sup>a</sup> Cholvastin [RA] <sup>a</sup> Pravastatin AN [EA] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Auro-Pravastatin 20 [DO] <sup>a</sup> Cholstat 20 [AF] <sup>a</sup> Lipostat 20 [RF] <sup>a</sup> Pravastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Pravastatin [TW]
			<sup>b</sup> 2.96	16.49	14.74	<sup>a</sup> Pravachol [RW]	

**pravastatin sodium 10 mg tablet, 30**

2833D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.63	13.84	<sup>a</sup> APO-Pravastatin [TX] <sup>a</sup> Chem mart Pravastatin [CH] <sup>a</sup> Pravastatin AN [EA] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Auro-Pravastatin 10 [DO] <sup>a</sup> Lipostat 10 [RF] <sup>a</sup> Pravastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Pravastatin [TW]
			<sup>b</sup> 2.94	15.57	13.84	<sup>a</sup> Pravachol [RW]	
			<sup>b</sup> 2.95	15.58	13.84	<sup>a</sup> Cholstat 10 [AF]	

**pravastatin sodium 40 mg tablet, 30**

8197K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14.89	16.10	<sup>a</sup> APO-Pravastatin [TX] <sup>a</sup> Chem mart Pravastatin [CH] <sup>a</sup> Cholvastin [RA] <sup>a</sup> Pravastatin AN [EA] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Auro-Pravastatin 40 [DO] <sup>a</sup> Cholstat 40 [AF] <sup>a</sup> Lipostat 40 [RF] <sup>a</sup> Pravastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Pravastatin [TW]
			<sup>b</sup> 3.01	17.90	16.10	<sup>a</sup> Pravachol [RW]	

**pravastatin sodium 80 mg tablet, 30**

8829Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.93	18.14	<sup>a</sup> APO-Pravastatin [TX] <sup>a</sup> Chem mart Pravastatin [CH] <sup>a</sup> Pravastatin AN [EA] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Auro-Pravastatin 80 [DO] <sup>a</sup> Lipostat 80 [RF] <sup>a</sup> Pravastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Pravastatin [TW]
			<sup>b</sup> 3.01	19.94	18.14	<sup>a</sup> Pravachol [RW]	

▪ **PRAVASTATIN**

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**pravastatin sodium 20 mg tablet, 30**

9238F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.53	14.74	<sup>a</sup> APO-Pravastatin [TX] <sup>a</sup> Chem mart Pravastatin [CH] <sup>a</sup> Cholvastin [RA] <sup>a</sup> Pravastatin AN [EA] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Auro-Pravastatin 20 [DO] <sup>a</sup> Cholstat 20 [AF] <sup>a</sup> Lipostat 20 [RF] <sup>a</sup> Pravastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Pravastatin [TW]

<sup>b</sup>2.96 16.49 14.74 <sup>a</sup> Pravachol [RW]

**pravastatin sodium 10 mg tablet, 30**

9237E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.63	13.84	<sup>a</sup> APO-Pravastatin [TX] <sup>a</sup> Chem mart Pravastatin [CH] <sup>a</sup> Pravastatin AN [EA] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Auro-Pravastatin 10 [DO] <sup>a</sup> Lipostat 10 [RF] <sup>a</sup> Pravastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Pravastatin [TW]

<sup>b</sup>2.94 15.57 13.84 <sup>a</sup> Pravachol [RW]

<sup>b</sup>2.95 15.58 13.84 <sup>a</sup> Cholstat 10 [AF]

**pravastatin sodium 40 mg tablet, 30**

9239G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.89	16.10	<sup>a</sup> APO-Pravastatin [TX] <sup>a</sup> Chem mart Pravastatin [CH] <sup>a</sup> Cholvastin [RA] <sup>a</sup> Pravastatin AN [EA] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Auro-Pravastatin 40 [DO] <sup>a</sup> Cholstat 40 [AF] <sup>a</sup> Lipostat 40 [RF] <sup>a</sup> Pravastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Pravastatin [TW]

<sup>b</sup>3.01 17.90 16.10 <sup>a</sup> Pravachol [RW]

**pravastatin sodium 80 mg tablet, 30**

9240H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	16.93	18.14	<sup>a</sup> APO-Pravastatin [TX] <sup>a</sup> Chem mart Pravastatin [CH] <sup>a</sup> Pravastatin AN [EA] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Auro-Pravastatin 80 [DO] <sup>a</sup> Lipostat 80 [RF] <sup>a</sup> Pravastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Pravastatin [TW]

<sup>b</sup>3.01 19.94 18.14 <sup>a</sup> Pravachol [RW]

**▪ ROSUVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**rosuvastatin 20 mg tablet, 30**

2574L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.95	20.16	<sup>a</sup> APO-Rosuvastatin [TX] <sup>a</sup> Cavstat [AF] <sup>a</sup> Crestor [AP] <sup>a</sup> Rosuvastatin AMNEAL [EF] <sup>a</sup> Rosuvastatin generichealth [HQ] <sup>a</sup> Terry White Chemists Rosuvastatin [TW]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB] <sup>a</sup> Chem mart Rosuvastatin [CH] <sup>a</sup> Crosuva 20 [ZP] <sup>a</sup> Rosuvastatin-DRLA [RI] <sup>a</sup> Rosuvastatin GH [GQ]

**rosuvastatin 5 mg tablet, 30**

2606E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14.85	16.06	<sup>a</sup> APO-Rosuvastatin [TX] <sup>a</sup> Cavstat [AF] <sup>a</sup> Crestor [AP] <sup>a</sup> Rosuvastatin AMNEAL [EF] <sup>a</sup> Rosuvastatin generichealth [HQ] <sup>a</sup> Terry White Chemists Rosuvastatin [TW]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB] <sup>a</sup> Chem mart Rosuvastatin [CH] <sup>a</sup> Crosuva 5 [ZP] <sup>a</sup> Rosuvastatin-DRLA [RI] <sup>a</sup> Rosuvastatin GH [GQ]

**rosuvastatin 40 mg tablet, 30**

2594M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.30	23.51	<sup>a</sup> APO-Rosuvastatin [TX] <sup>a</sup> Cavstat [AF] <sup>a</sup> Crestor [AP] <sup>a</sup> Rosuvastatin AMNEAL [EF] <sup>a</sup> Rosuvastatin generichealth [HQ] <sup>a</sup> Terry White Chemists Rosuvastatin [TW]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB] <sup>a</sup> Chem mart Rosuvastatin [CH] <sup>a</sup> Crosuva 40 [ZP] <sup>a</sup> Rosuvastatin-DRLA [RI] <sup>a</sup> Rosuvastatin GH [GQ]

**rosuvastatin 10 mg tablet, 30**

2628H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.62	17.83	<sup>a</sup> APO-Rosuvastatin [TX] <sup>a</sup> Cavstat [AF] <sup>a</sup> Crestor [AP] <sup>a</sup> Rosuvastatin AMNEAL [EF] <sup>a</sup> Rosuvastatin generichealth [HQ] <sup>a</sup> Terry White Chemists Rosuvastatin [TW]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB] <sup>a</sup> Chem mart Rosuvastatin [CH] <sup>a</sup> Crosuva 10 [ZP] <sup>a</sup> Rosuvastatin-DRLA [RI] <sup>a</sup> Rosuvastatin GH [GQ]

**▪ ROSUVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

**rosuvastatin 20 mg tablet, 30**

9044B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.95	20.16	<sup>a</sup> APO-Rosuvastatin [TX] <sup>a</sup> Cavstat [AF] <sup>a</sup> Crestor [AP] <sup>a</sup> Rostor 20 [DO] <sup>a</sup> Rosuvastatin-DRLA [RI] <sup>a</sup> Rosuvastatin GH [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB] <sup>a</sup> Chem mart Rosuvastatin [CH] <sup>a</sup> Crosuva 20 [ZP] <sup>a</sup> Rosuvastatin AMNEAL [EF] <sup>a</sup> Rosuvastatin generichealth [HQ] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> Terry White Chemists Rosuvastatin [TW]

**rosuvastatin 5 mg tablet, 30**

9042X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.85	16.06	<sup>a</sup> APO-Rosuvastatin [TX] <sup>a</sup> Cavstat [AF] <sup>a</sup> Crestor [AP] <sup>a</sup> Rostor 5 [DO] <sup>a</sup> Rosuvastatin-DRLA [RI] <sup>a</sup> Rosuvastatin GH [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB] <sup>a</sup> Chem mart Rosuvastatin [CH] <sup>a</sup> Crosuva 5 [ZP] <sup>a</sup> Rosuvastatin AMNEAL [EF] <sup>a</sup> Rosuvastatin generichealth [HQ] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> Terry White Chemists Rosuvastatin [TW]

**rosuvastatin 40 mg tablet, 30**

9045C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.30	23.51	<sup>a</sup> APO-Rosuvastatin [TX] <sup>a</sup> Cavstat [AF] <sup>a</sup> Crestor [AP] <sup>a</sup> Rostor 40 [DO] <sup>a</sup> Rosuvastatin-DRLA [RI] <sup>a</sup> Rosuvastatin GH [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB] <sup>a</sup> Chem mart Rosuvastatin [CH] <sup>a</sup> Crosuva 40 [ZP] <sup>a</sup> Rosuvastatin AMNEAL [EF] <sup>a</sup> Rosuvastatin generichealth [HQ] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> Terry White Chemists Rosuvastatin [TW]

**rosuvastatin 10 mg tablet, 30**

9043Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.62	17.83	<sup>a</sup> APO-Rosuvastatin [TX] <sup>a</sup> Cavstat [AF] <sup>a</sup> Crestor [AP] <sup>a</sup> Rostor 10 [DO] <sup>a</sup> Rosuvastatin-DRLA [RI] <sup>a</sup> Rosuvastatin GH [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB] <sup>a</sup> Chem mart Rosuvastatin [CH] <sup>a</sup> Crosuva 10 [ZP] <sup>a</sup> Rosuvastatin AMNEAL [EF] <sup>a</sup> Rosuvastatin generichealth [HQ] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> Terry White Chemists Rosuvastatin [TW]

▪ **ROSUVASTATIN**

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**rosuvastatin 20 mg tablet, 30**

2609H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	18.95	20.16	<sup>a</sup> APO-Rosuvastatin [TX]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB]
						<sup>a</sup> Cavstat [AF]	<sup>a</sup> Chem mart Rosuvastatin [CH]
						<sup>a</sup> Crestor [AP]	<sup>a</sup> Crosuva 20 [ZP]
						<sup>a</sup> Rosuvastatin AMNEAL [EF]	<sup>a</sup> Rosuvastatin-DRLA [RI]
						<sup>a</sup> Rosuvastatin generichealth [HQ]	<sup>a</sup> Rosuvastatin GH [GQ]
						<sup>a</sup> Terry White Chemists Rosuvastatin [TW]	

**rosuvastatin 5 mg tablet, 30**

2590H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.85	16.06	<sup>a</sup> APO-Rosuvastatin [TX]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB]
						<sup>a</sup> Cavstat [AF]	<sup>a</sup> Chem mart Rosuvastatin [CH]
						<sup>a</sup> Crestor [AP]	<sup>a</sup> Crosuva 5 [ZP]
						<sup>a</sup> Rosuvastatin AMNEAL [EF]	<sup>a</sup> Rosuvastatin-DRLA [RI]
						<sup>a</sup> Rosuvastatin generichealth [HQ]	<sup>a</sup> Rosuvastatin GH [GQ]
						<sup>a</sup> Terry White Chemists Rosuvastatin [TW]	

**rosuvastatin 40 mg tablet, 30**

2636R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	22.30	23.51	<sup>a</sup> APO-Rosuvastatin [TX]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB]
						<sup>a</sup> Cavstat [AF]	<sup>a</sup> Chem mart Rosuvastatin [CH]
						<sup>a</sup> Crestor [AP]	<sup>a</sup> Crosuva 40 [ZP]
						<sup>a</sup> Rosuvastatin AMNEAL [EF]	<sup>a</sup> Rosuvastatin-DRLA [RI]
						<sup>a</sup> Rosuvastatin generichealth [HQ]	<sup>a</sup> Rosuvastatin GH [GQ]
						<sup>a</sup> Terry White Chemists Rosuvastatin [TW]	

**rosuvastatin 10 mg tablet, 30**

2584B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	16.62	17.83	<sup>a</sup> APO-Rosuvastatin [TX]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB]
						<sup>a</sup> Cavstat [AF]	<sup>a</sup> Chem mart Rosuvastatin [CH]
						<sup>a</sup> Crestor [AP]	<sup>a</sup> Crosuva 10 [ZP]
						<sup>a</sup> Rosuvastatin AMNEAL [EF]	<sup>a</sup> Rosuvastatin-DRLA [RI]
						<sup>a</sup> Rosuvastatin generichealth [HQ]	<sup>a</sup> Rosuvastatin GH [GQ]
						<sup>a</sup> Terry White Chemists Rosuvastatin [TW]	

▪ **ROSUVASTATIN**

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements, **AND**
- The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

**rosuvastatin 20 mg tablet, 30**

3404E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	18.95	20.16	<sup>a</sup> APO-Rosuvastatin [TX]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB]
						<sup>a</sup> Cavstat [AF]	<sup>a</sup> Chem mart Rosuvastatin [CH]
						<sup>a</sup> Crestor [AP]	<sup>a</sup> Crosuva 20 [ZP]
						<sup>a</sup> Rostor 20 [DO]	<sup>a</sup> Rosuvastatin AMNEAL [EF]
						<sup>a</sup> Rosuvastatin-DRLA [RI]	<sup>a</sup> Rosuvastatin generichealth [HQ]
						<sup>a</sup> Rosuvastatin GH [GQ]	<sup>a</sup> Rosuvastatin RBX [RA]
						<sup>a</sup> Rosuvastatin Sandoz [SZ]	<sup>a</sup> Terry White Chemists Rosuvastatin [TW]

**rosuvastatin 5 mg tablet, 30**

3402C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.85	16.06	<sup>a</sup> APO-Rosuvastatin [TX]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB]
						<sup>a</sup> Cavstat [AF]	<sup>a</sup> Chem mart Rosuvastatin [CH]
						<sup>a</sup> Crestor [AP]	<sup>a</sup> Crosuva 5 [ZP]
						<sup>a</sup> Rostor 5 [DO]	<sup>a</sup> Rosuvastatin AMNEAL [EF]
						<sup>a</sup> Rosuvastatin-DRLA [RI]	<sup>a</sup> Rosuvastatin generichealth [HQ]
						<sup>a</sup> Rosuvastatin GH [GQ]	<sup>a</sup> Rosuvastatin RBX [RA]
						<sup>a</sup> Rosuvastatin Sandoz [SZ]	<sup>a</sup> Terry White Chemists Rosuvastatin [TW]

**rosuvastatin 40 mg tablet, 30**

3405F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	22.30	23.51	<sup>a</sup> APO-Rosuvastatin [TX]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB]
						<sup>a</sup> Cavstat [AF]	<sup>a</sup> Chem mart Rosuvastatin [CH]
						<sup>a</sup> Crestor [AP]	<sup>a</sup> Crosuva 40 [ZP]
						<sup>a</sup> Rostor 40 [DO]	<sup>a</sup> Rosuvastatin AMNEAL [EF]
						<sup>a</sup> Rosuvastatin-DRLA [RI]	<sup>a</sup> Rosuvastatin generichealth [HQ]
						<sup>a</sup> Rosuvastatin GH [GQ]	<sup>a</sup> Rosuvastatin RBX [RA]
						<sup>a</sup> Rosuvastatin Sandoz [SZ]	<sup>a</sup> Terry White Chemists Rosuvastatin [TW]

**rosuvastatin 10 mg tablet, 30**

3403D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	16.62	17.83	<sup>a</sup> APO-Rosuvastatin [TX]	<sup>a</sup> Blooms the Chemist Rosuvastatin [IB]
						<sup>a</sup> Cavstat [AF]	<sup>a</sup> Chem mart Rosuvastatin [CH]
						<sup>a</sup> Crestor [AP]	<sup>a</sup> Crosuva 10 [ZP]
						<sup>a</sup> Rostor 10 [DO]	<sup>a</sup> Rosuvastatin AMNEAL [EF]
						<sup>a</sup> Rosuvastatin-DRLA [RI]	<sup>a</sup> Rosuvastatin generichealth [HQ]
						<sup>a</sup> Rosuvastatin GH [GQ]	<sup>a</sup> Rosuvastatin RBX [RA]
						<sup>a</sup> Rosuvastatin Sandoz [SZ]	<sup>a</sup> Terry White Chemists Rosuvastatin [TW]

▪ **SIMVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**simvastatin 10 mg tablet, 30**

2011W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.21	13.42	<sup>a</sup> APO-Simvastatin [TX]	<sup>a</sup> Auro-Simvastatin 10 [DO]
						<sup>a</sup> Chem mart Simvastatin [CH]	<sup>a</sup> Ransim [RA]
						<sup>a</sup> Simvacor 10 [CR]	<sup>a</sup> Simvar 10 [RW]
						<sup>a</sup> Simvastatin AN [EA]	<sup>a</sup> Simvastatin-GA 10 [ED]
						<sup>a</sup> Simvastatin generichealth [GQ]	<sup>a</sup> Simvastatin Sandoz [SZ]
						<sup>a</sup> Terry White Chemists Simvastatin [TW]	<sup>a</sup> Zimstat [AF]
			<sup>b</sup> 5.33	17.54	13.42	<sup>a</sup> Lipex 10 [FR]	<sup>a</sup> Zocor [MK]

**simvastatin 5 mg tablet, 30**

2013Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.91	13.12	<sup>a</sup> Simvastatin Sandoz [SZ]	<sup>a</sup> Zimstat [AF]

**simvastatin 80 mg tablet, 30**

8313M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.42	15.63	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Chem mart Simvastatin [CH] <sup>a</sup> Simvacor 80 [CR] <sup>a</sup> Simvastatin AN [EA] <sup>a</sup> Simvastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Simvastatin [TW]	<sup>a</sup> Auro-Simvastatin 80 [DO] <sup>a</sup> Ransim [RA] <sup>a</sup> Simvar 80 [RW] <sup>a</sup> Simvastatin-GA 80 [ED] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]
			<sup>b</sup> 8.46	22.88	15.63	<sup>a</sup> Lipex 80 [FR]	<sup>a</sup> Zocor [MK]

**simvastatin 20 mg tablet, 30**

2012X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.71	13.92	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Chem mart Simvastatin [CH] <sup>a</sup> Simvacor 20 [CR] <sup>a</sup> Simvastatin AN [EA] <sup>a</sup> Simvastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Simvastatin [TW]	<sup>a</sup> Auro-Simvastatin 20 [DO] <sup>a</sup> Ransim [RA] <sup>a</sup> Simvar 20 [RW] <sup>a</sup> Simvastatin-GA 20 [ED] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]
			<sup>b</sup> 7.50	20.21	13.92	<sup>a</sup> Lipex 20 [FR]	<sup>a</sup> Zocor [MK]

**simvastatin 40 mg tablet, 30**

8173E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.42	14.63	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Chem mart Simvastatin [CH] <sup>a</sup> Simvacor 40 [CR] <sup>a</sup> Simvastatin AN [EA] <sup>a</sup> Simvastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Simvastatin [TW]	<sup>a</sup> Auro-Simvastatin 40 [DO] <sup>a</sup> Ransim [RA] <sup>a</sup> Simvar 40 [RW] <sup>a</sup> Simvastatin-GA 40 [ED] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]
			<sup>b</sup> 7.50	20.92	14.63	<sup>a</sup> Lipex 40 [FR]	<sup>a</sup> Zocor [MK]

▪ **SIMVASTATIN**

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**simvastatin 10 mg tablet, 30**

9242K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.21	13.42	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Chem mart Simvastatin [CH] <sup>a</sup> Simvacor 10 [CR] <sup>a</sup> Simvastatin AN [EA] <sup>a</sup> Simvastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Simvastatin [TW]	<sup>a</sup> Auro-Simvastatin 10 [DO] <sup>a</sup> Ransim [RA] <sup>a</sup> Simvar 10 [RW] <sup>a</sup> Simvastatin-GA 10 [ED] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]
			<sup>b</sup> 5.33	17.54	13.42	<sup>a</sup> Lipex 10 [FR]	<sup>a</sup> Zocor [MK]

**simvastatin 5 mg tablet, 30**

9241J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	11.91	13.12	<sup>a</sup> Simvastatin Sandoz [SZ]	<sup>a</sup> Zimstat [AF]

**simvastatin 80 mg tablet, 30**

9245N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.42	15.63	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Chem mart Simvastatin [CH]	<sup>a</sup> Auro-Simvastatin 80 [DO] <sup>a</sup> Ransim [RA]

- <sup>a</sup> Simvacor 80 [CR]
- <sup>a</sup> Simvastatin AN [EA]
- <sup>a</sup> Simvastatin generichealth [GQ]
- <sup>a</sup> Terry White Chemists Simvastatin [TW]
- <sup>a</sup> Lipex 80 [FR]
- <sup>a</sup> Simvar 80 [RW]
- <sup>a</sup> Simvastatin-GA 80 [ED]
- <sup>a</sup> Simvastatin Sandoz [SZ]
- <sup>a</sup> Zimstat [AF]
- <sup>a</sup> Zocor [MK]

<sup>b</sup>8.46      22.88      15.63

**simvastatin 20 mg tablet, 30**

9243L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.71	13.92	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Chem mart Simvastatin [CH] <sup>a</sup> Simvacor 20 [CR] <sup>a</sup> Simvastatin AN [EA] <sup>a</sup> Simvastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Simvastatin [TW]	<sup>a</sup> Auro-Simvastatin 20 [DO] <sup>a</sup> Ransim [RA] <sup>a</sup> Simvar 20 [RW] <sup>a</sup> Simvastatin-GA 20 [ED] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]
			<sup>b</sup> 7.50	20.21	13.92	<sup>a</sup> Lipex 20 [FR]	<sup>a</sup> Zocor [MK]

**simvastatin 40 mg tablet, 30**

9244M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.42	14.63	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Chem mart Simvastatin [CH] <sup>a</sup> Simvacor 40 [CR] <sup>a</sup> Simvastatin AN [EA] <sup>a</sup> Simvastatin generichealth [GQ] <sup>a</sup> Terry White Chemists Simvastatin [TW]	<sup>a</sup> Auro-Simvastatin 40 [DO] <sup>a</sup> Ransim [RA] <sup>a</sup> Simvar 40 [RW] <sup>a</sup> Simvastatin-GA 40 [ED] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]
			<sup>b</sup> 7.50	20.92	14.63	<sup>a</sup> Lipex 40 [FR]	<sup>a</sup> Zocor [MK]

**Fibrates**

■ **FENOFIBRATE**

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**fenofibrate 48 mg tablet, 60**

9022W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	30.60	31.81	Lipidil [GO]

**fenofibrate 145 mg tablet, 30**

9023X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	40.38	38.80	Lipidil [GO]

■ **FENOFIBRATE**

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**fenofibrate 48 mg tablet, 60**

9246P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	30.60	31.81	Lipidil [GO]

**fenofibrate 145 mg tablet, 30**

9247Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	40.38	38.80	Lipidil [GO]

▪ **GEMFIBROZIL**

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**gemfibrozil 600 mg tablet, 60**

1453L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.99	22.20	<sup>a</sup> Ausgem [RW]	<sup>a</sup> Lipigem [AF]

▪ **GEMFIBROZIL**

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**gemfibrozil 600 mg tablet, 60**

9248R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	20.99	22.20	<sup>a</sup> Ausgem [RW]	<sup>a</sup> Lipigem [AF]

*Bile acid sequestrants*

▪ **CHOLESTYRAMINE**

**cholestyramine 4 g powder for oral liquid, 50 sachets**

2967E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*80.51	38.80	Questran Lite [QA]

▪ **CHOLESTYRAMINE**

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

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

**Restricted benefit**

Primary hypercholesterolaemia

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**cholestyramine 4 g powder for oral liquid, 50 sachets**

9249T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*80.51	38.80	Questran Lite [QA]

*Other lipid modifying agents*

▪ **EVOLOCUMAB**

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after at least 3 months of treatment at a maximum tolerated dose of an HMG CoA reductase inhibitor (statin), in conjunction with dietary therapy and exercise; OR
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after having developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of statin treatment; OR

- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre and must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

**Treatment criteria:**

- Must be treated by a consultant physician or in consultation with a consultant physician.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The date of the consultation with a consultant physician must be no more than 6 months prior to the application for a PBS authority. The full name of the consultant physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level must be provided at the time of application and must be no more than 2 months old. With the exception of patients contraindicated to a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

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

- a) A completed authority prescription form; and
- b) A completed Familial homozygous hypercholesterolaemia Initial PBS Authority Application - Supporting Information Form; and
- c) The date of consultation and the full name of the consultant physician; and
- d) A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and
- e) The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse event or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge**

11193D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	943.14	38.80	Repatha [AN]

▪ **EVOLOCUMAB**

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after at least 3 months of treatment at a maximum tolerated dose of an HMG CoA reductase inhibitor (statin), in conjunction with dietary therapy and exercise; OR
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after having developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of statin treatment; OR
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre and must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

**Treatment criteria:**

- Must be treated by a consultant physician or in consultation with a consultant physician.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The date of the consultation with a consultant physician must be no more than 6 months prior to the application for a PBS authority. The full name of the consultant physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level must be provided at the time of application and must be no more than 2 months old. With the exception of patients contraindicated to a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

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

- a) A completed authority prescription form; and
- b) A completed Familial homozygous hypercholesterolaemia Initial PBS Authority Application - Supporting Information Form; and
- c) The date of consultation and the full name of the consultant physician; and
- d) A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and
- e) The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse event or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre after at least 3 months of treatment at a maximum tolerated dose of an HMG CoA reductase inhibitor (statin), in conjunction with dietary therapy and exercise, prior to initiation of treatment with this drug; OR
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre after having developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of statin treatment, prior to initiation of treatment with this drug; OR
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre prior to initiation of treatment with this drug, and must be contraindicated to treatment with an HMG CoA reductase inhibitor (statin).

**Treatment criteria:**

- Must be treated by a consultant physician or in consultation with a consultant physician.

The date of the consultation with a consultant physician must be no more than 6 months prior to the application for a PBS authority. The full name of the consultant physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level prior to initiation of treatment with this drug must be provided at the time of application. With the exception of patients contraindicated to a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

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

- a) A completed authority prescription form; and
- b) A completed Familial homozygous hypercholesterolaemia Initial PBS 'Grandfather' Authority Application - Supporting Information Form; and
- c) The date of consultation and the full name of the consultant physician; and
- d) A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and
- e) The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse event or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### evolocumab 140 mg/mL injection, 1 mL injection device

10958R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*943.15	38.80	Repatha [AN]

### ■ EZETIMIBE

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

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

#### **Authority required (STREAMLINED)**

**5537**

Hypercholesterolaemia

#### **Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

#### **Authority required (STREAMLINED)**

**5543**

Hypercholesterolaemia

#### **Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**5538**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**5544**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**5594**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****5586**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****5575**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****5576**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

**Authority required (STREAMLINED)****5562**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; OR
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**Authority required (STREAMLINED)****5563**

Homozygous sitosterolaemia

**Authority required (STREAMLINED)**

**5577**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin).

**ezetimibe 10 mg tablet, 30**

8757X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	66.84	38.80	Ezetrol [MK]

**LIPID MODIFYING AGENTS, COMBINATIONS**

*HMG CoA reductase inhibitors in combination with other lipid modifying agents*

▪ **EZETIMIBE + ATORVASTATIN**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4068**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****4069**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****4096**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****4120**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4121**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4097**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**ezetimibe 10 mg + atorvastatin 20 mg tablet, 30**

10393B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	69.10	38.80	Atozet [MK]

**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

10376D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	71.38	38.80	Atozet [MK]

**ezetimibe 10 mg + atorvastatin 40 mg tablet, 30**

10377E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	70.01	38.80	Atozet [MK]

**■ EZETIMIBE + ATORVASTATIN**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4068**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****4086**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****4069**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)****4096**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that

threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4121**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4097**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

**4353**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the atorvastatin dose.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

10392Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	68.37	38.80	Atozet [MK]

▪ **EZETIMIBE + SIMVASTATIN**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4068**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4096**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4121**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4097**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

8882L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	70.17	38.80	Vytorin [MK]

**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

8881K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	69.17	38.80	Vytorin [MK]

▪ **EZETIMIBE + SIMVASTATIN**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4068**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that

threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4096**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4121**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4097**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

**4147**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**ezetimibe 10 mg + simvastatin 20 mg tablet, 30**

9484E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	68.46	38.80	Vytorin [MK]

**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

9483D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	67.96	38.80	Vytorin [MK]

▪ **ROSUVASTATIN (&) EZETIMIBE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4068**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4096**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4121**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4097**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack**

10207F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	71.83	38.80	Rosuzet Composite Pack [MK]

**rosuvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack**

10201X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	70.33	38.80	Rosuzet Composite Pack [MK]

**rosuvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack**

10208G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	69.32	38.80	Rosuzet Composite Pack [MK]

**▪ ROSUVASTATIN (&) EZETIMIBE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**4068**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that

threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4096**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4121**

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4097**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

**4147**

Hypercholesterolaemia

**Clinical criteria:**

- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**rosuvastatin 5 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack**

10204C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	68.52	38.80	Rosuzet Composite Pack [MK]

*HMG CoA reductase inhibitors, other combinations*

▪ **AMLODIPINE + ATORVASTATIN**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Angina

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be one in whom blood pressure is inadequately controlled with other classes of antihypertensive agents, **AND**
- The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Angina

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must have angina which is inadequately controlled with other classes of anti-anginal agents, **AND**
- The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be intolerant of the side effects of other classes of antihypertensive agents, **AND**
- Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

**Restricted benefit**

Angina

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be intolerant of the side effects of other classes of anti-anginal agents, **AND**
- Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

**amlodipine 10 mg + atorvastatin 20 mg tablet, 30**

9054M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.93	16.14	<sup>a</sup> APO-Amlodipine/Atorvastatin 10/20 [TX]	<sup>a</sup> Blooms the Chemist Amlodipine/Atorvastatin 10/20 [IB]
						<sup>a</sup> Cadivast 10/20 [AF]	
			<sup>B</sup> 3.00	17.93	16.14	<sup>a</sup> Caduet 10/20 [PF]	

**amlodipine 10 mg + atorvastatin 80 mg tablet, 30**

9056P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.21	18.42	<sup>a</sup> APO-Amlodipine/Atorvastatin 10/80 [TX]	<sup>a</sup> Blooms the Chemist Amlodipine/Atorvastatin 10/80 [IB]
						<sup>a</sup> Cadivast 10/80 [AF]	
			<sup>B</sup> 3.00	20.21	18.42	<sup>a</sup> Caduet 10/80 [PF]	

**amlodipine 5 mg + atorvastatin 20 mg tablet, 30**

9050H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.24	15.45	<sup>a</sup> APO-Amlodipine/Atorvastatin 5/20 [TX]	<sup>a</sup> Blooms the Chemist Amlodipine/Atorvastatin 5/20 [IB]
						<sup>a</sup> Cadivast 5/20 [AF]	
			<sup>B</sup> 3.00	17.24	15.45	<sup>a</sup> Caduet 5/20 [PF]	

**amlodipine 5 mg + atorvastatin 40 mg tablet, 30**

9051J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.15	16.36	<sup>a</sup> APO-Amlodipine/Atorvastatin 5/40 [TX]	<sup>a</sup> Blooms the Chemist Amlodipine/Atorvastatin 5/40 [IB]
						<sup>a</sup> Cadivast 5/40 [AF]	

# DERMATOLOGICALS

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<sup>B</sup> 3.00    18.15    16.36 <sup>a</sup> Caduet 5/40 [PF]							
<b>amlodipine 5 mg + atorvastatin 10 mg tablet, 30</b>							
9049G	1	5	..	13.51	14.72	<sup>a</sup> APO-Amlodipine/Atorvastatin 5/10 [TX]	<sup>a</sup> Blooms the Chemist Amlodipine/Atorvastatin 5/10 [IB]
<sup>B</sup> 3.00    16.51    14.72 <sup>a</sup> Cadivast 5/10 [AF]							
<sup>a</sup> Caduet 5/10 [PF]							
<b>amlodipine 10 mg + atorvastatin 40 mg tablet, 30</b>							
9055N	1	5	..	15.84	17.05	<sup>a</sup> APO-Amlodipine/Atorvastatin 10/40 [TX]	<sup>a</sup> Blooms the Chemist Amlodipine/Atorvastatin 10/40 [IB]
<sup>B</sup> 3.00    18.84    17.05 <sup>a</sup> Cadivast 10/40 [AF]							
<sup>a</sup> Caduet 10/40 [PF]							
<b>amlodipine 10 mg + atorvastatin 10 mg tablet, 30</b>							
9053L	1	5	..	14.20	15.41	<sup>a</sup> APO-Amlodipine/Atorvastatin 10/10 [TX]	<sup>a</sup> Blooms the Chemist Amlodipine/Atorvastatin 10/10 [IB]
<sup>B</sup> 3.00    17.20    15.41 <sup>a</sup> Cadivast 10/10 [AF]							
<sup>a</sup> Caduet 10/10 [PF]							
<b>amlodipine 5 mg + atorvastatin 80 mg tablet, 30</b>							
9052K	1	5	..	16.52	17.73	<sup>a</sup> APO-Amlodipine/Atorvastatin 5/80 [TX]	<sup>a</sup> Blooms the Chemist Amlodipine/Atorvastatin 5/80 [IB]
<sup>B</sup> 3.00    19.52    17.73 <sup>a</sup> Cadivast 5/80 [AF]							
<sup>a</sup> Caduet 5/80 [PF]							

**DERMATOLOGICALS**  
**ANTIFUNGALS FOR DERMATOLOGICAL USE**  
**ANTIFUNGALS FOR TOPICAL USE**  
*Antibiotics*

**■ NYSTATIN**

**Authority required (STREAMLINED)**

**6434**

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**nystatin 100 000 units/g cream, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1698J	2	3	..	*21.11	22.32	Mycostatin [FM]

*Imidazole and triazole derivatives*

**■ KETOCONAZOLE**

**Authority required (STREAMLINED)**

**6434**

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**ketoconazole 2% cream, 30 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9024Y	‡1	2	..	25.63	26.84	Nizoral 2% Cream [JT]

**ketoconazole 2% shampoo, 60 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1574W	‡1	1	..	21.58	22.79	Nizoral 2% [JT]

**ketoconazole 1% shampoo, 100 mL**

9025B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	20.95	22.16	Nizoral 1% [JT]

**■ MICONAZOLE****Authority required (STREAMLINED)****6434**

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**miconazole nitrate 2% cream, 30 g**

9027D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	18.59	19.80	Daktarin [JT]

**miconazole nitrate 2% dusting powder, 30 g**

9029F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	19.32	20.53	Daktarin [JT]

**miconazole 2% solution, 30 mL**

9031H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	22.56	23.77	Daktarin Tincture [JT]

**miconazole nitrate 2% cream, 70 g**

9028E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	20.27	21.48	Daktarin [JT]

*Other antifungals for topical use***■ TERBINAFINE****Authority required (STREAMLINED)****6434**

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)****6412**

Fungal or yeast infection

**Clinical criteria:**

- The condition must be fungal; OR
- The condition must be due to yeast.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine hydrochloride 1% cream, 15 g**

9160D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*37.99	38.80	<sup>a</sup> Lamisil [GK]

**ANTIFUNGALS FOR SYSTEMIC USE***Antifungals for systemic use***■ GRISEOFULVIN****griseofulvin 125 mg tablet, 100**

1460W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	27.15	28.36	Grisovin [QA]

**griseofulvin 500 mg tablet, 28**

2982Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	28.09	29.30	Grisovin 500 [QA]

**■ TERBINAFINE****Authority required**

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required**

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment, **AND**
- Patient must have failed to respond to griseofulvin.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine 250 mg tablet, 42**

2285G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	30.00	31.21	<sup>a</sup> APO-Terbinafine [TX] <sup>a</sup> Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] <sup>a</sup> Tamsil [RW] <sup>a</sup> Terbinafine-DRLA [RZ] <sup>a</sup> Terbinafine Sandoz [SZ]	<sup>a</sup> GenRx Terbinafine [GX] <sup>a</sup> Sebifin 250 [RA]  <sup>a</sup> Terbinafine AN [EA] <sup>a</sup> Terbinafine GH [GQ] <sup>a</sup> Tinasil [AF]

**■ TERBINAFINE**

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

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

**Authority required**

Onychomycosis

**Clinical criteria:**

- The condition must be proximal or extensive (greater than 80% nail involvement), **AND**
- Patient must have failed to respond to topical treatment, **AND**
- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old

**terbinafine 250 mg tablet, 42**

2804N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	30.00	31.21	<sup>a</sup> APO-Terbinafine [TX] <sup>a</sup> Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] <sup>a</sup> Tamsil [RW] <sup>a</sup> Terbinafine-DRLA [RZ] <sup>a</sup> Terbinafine Sandoz [SZ]	<sup>a</sup> GenRx Terbinafine [GX] <sup>a</sup> Sebifin 250 [RA]  <sup>a</sup> Terbinafine AN [EA] <sup>a</sup> Terbinafine GH [GQ] <sup>a</sup> Tinasil [AF]

**■ ANTIPSORIATICS****ANTIPSORIATICS FOR TOPICAL USE***Tars***■ PREPARED COAL TAR****coal tar prepared 2% foam, 100 g**

10225E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	2	..	34.27	35.48	Scytera [RZ]

**prepared coal tar 1% w/w lotion, 100 mL**

8864M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	2	..	33.11	34.32	Exorex [GN]

*Other antipsoriatics for topical use***■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6873**

Chronic stable plaque type psoriasis vulgaris

**Clinical criteria:**

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy, **AND**

- Patient must require more than 30 grams of product per month.

### calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g

10075G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	63.11	38.80	Daivobet 50/500 gel [LO]

### ■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

#### Note Continuing Therapy Only:

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

#### Restricted benefit

Chronic stable plaque type psoriasis vulgaris

#### Clinical criteria:

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

### calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g

5276Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	37.10	38.31	Daivobet 50/500 gel [LO]

### calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g

9494Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	37.10	38.31	<sup>a</sup> Calcipotriol/Betamethasone Sandoz 50/500 [SZ]	<sup>a</sup> Daivobet [LO]

### calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g

11091R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	83.33	38.80	Enstilar [LO]

## ANTIPSORIATICS FOR SYSTEMIC USE

### Retinoids for treatment of psoriasis

### ■ ACITRETIN

**Caution** This drug is a potent teratogen - pregnancy should be avoided for at least two years after cessation of therapy.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

#### Authority required (STREAMLINED)

5789

Severe intractable psoriasis

#### Authority required (STREAMLINED)

5727

Severe disorders of keratinisation

### acitretin 25 mg capsule, 100

2020H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	207.38	38.80	<sup>a</sup> Neotigason [UA] <sup>a</sup> ZETIN [RW]	<sup>a</sup> Novatin [TX]

### acitretin 10 mg capsule, 100

2019G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	107.34	38.80	<sup>a</sup> Neotigason [UA] <sup>a</sup> ZETIN [RW]	<sup>a</sup> Novatin [TX]

## ■ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

### CHEMOTHERAPEUTICS FOR TOPICAL USE

#### Sulfonamides

### ■ SILVER SULFADIAZINE

#### Restricted benefit

Infection

Treatment Phase: Prevention and treatment

#### Clinical criteria:

- The condition must be in partial or full skin thickness loss due to burns; OR
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

#### Restricted benefit

Stasis ulcers

# DERMATOLOGICALS

## silver sulfadiazine 1% cream, 50 g

9479X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	21.62	22.83	Flamazine [SN]

## ■ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

### CORTICOSTEROIDS, PLAIN

*Corticosteroids, weak (group I)*

#### ■ HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

#### hydrocortisone acetate 1% cream, 50 g

2881P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	12.95	14.16	<sup>a</sup> Cortic-DS 1% [FM]
			<sup>B</sup> 2.35	15.30	14.16	<sup>a</sup> Sigmacort [QA]

#### hydrocortisone acetate 1% ointment, 50 g

2882Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	12.95	14.16	<sup>a</sup> Cortic-DS 1% [FM]
			<sup>B</sup> 2.35	15.30	14.16	<sup>a</sup> Sigmacort [QA]

#### ■ HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

#### hydrocortisone acetate 1% cream, 50 g

5113D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	12.95	14.16	<sup>a</sup> Cortic-DS 1% [FM]
			<sup>B</sup> 2.35	15.30	14.16	<sup>a</sup> Sigmacort [QA]

#### hydrocortisone acetate 1% ointment, 50 g

5114E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	12.95	14.16	<sup>a</sup> Cortic-DS 1% [FM]
			<sup>B</sup> 2.35	15.30	14.16	<sup>a</sup> Sigmacort [QA]

*Corticosteroids, moderately potent (group II)*

#### ■ TRIAMCINOLONE

**Restricted benefit**

Corticosteroid-responsive dermatoses

#### triamcinolone acetonide 0.02% ointment, 100 g

2118L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*18.03	19.24	<sup>a</sup> Tricortone [FM]
			<sup>B</sup> 3.28	*21.31	19.24	<sup>a</sup> Aristocort 0.02% [QA]

#### triamcinolone acetonide 0.02% cream, 100 g

2117K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*18.03	19.24	<sup>a</sup> Tricortone [FM]
			<sup>B</sup> 3.28	*21.31	19.24	<sup>a</sup> Aristocort 0.02% [QA]

*Corticosteroids, potent (group III)*

#### ■ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

#### betamethasone (as dipropionate) 0.05% cream, 15 g

1115Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	16.93	18.14	<sup>a</sup> Elephrat [FR]
			<sup>B</sup> 2.45	19.38	18.14	<sup>a</sup> Diprosone [MK]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1119X	1	1	..	16.93	18.14	<sup>a</sup> Eleuphrat [FR]
			<sup>B</sup> 2.45	19.38	18.14	<sup>a</sup> Diprosone [MK]

**■ BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6232**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10824Q	2	5	..	*22.77	23.98	<sup>a</sup> Eleuphrat [FR]
			<sup>B</sup> 4.90	*27.67	23.98	<sup>a</sup> Diprosone [MK]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10795E	2	5	..	*22.77	23.98	<sup>a</sup> Eleuphrat [FR]
			<sup>B</sup> 4.90	*27.67	23.98	<sup>a</sup> Diprosone [MK]

**■ BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6246**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10800K	4	5	..	*34.47	35.68	<sup>a</sup> Eleuphrat [FR]
			<sup>B</sup> 9.80	*44.27	35.68	<sup>a</sup> Diprosone [MK]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10820L	4	5	..	*34.47	35.68	<sup>a</sup> Eleuphrat [FR]
			<sup>B</sup> 9.80	*44.27	35.68	<sup>a</sup> Diprosone [MK]

**■ BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10813D	6	5	..	*46.15	38.80	<sup>a</sup> Eleuphrat [FR]
			<sup>B</sup> 14.70	*60.85	38.80	<sup>a</sup> Diprosone [MK]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10821M	6	5	..	*46.15	38.80	<sup>a</sup> Eleuphrat [FR]
			<sup>B</sup> 14.70	*60.85	38.80	<sup>a</sup> Diprosone [MK]

## ■ BETAMETHASONE DIPROPIONATE

### Note Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**6263**

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

### betamethasone (as dipropionate) 0.05% cream, 15 g

10801L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*57.79	38.80	<sup>a</sup> Elephrat [FR]
			<sup>B</sup> 19.60	*77.39	38.80	<sup>a</sup> Diprosone [MK]

### betamethasone (as dipropionate) 0.05% ointment, 15 g

10816G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*57.79	38.80	<sup>a</sup> Elephrat [FR]
			<sup>B</sup> 19.60	*77.39	38.80	<sup>a</sup> Diprosone [MK]

## ■ BETAMETHASONE DIPROPIONATE

### Note Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**6231**

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

### betamethasone (as dipropionate) 0.05% cream, 15 g

10802M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*69.45	38.80	<sup>a</sup> Elephrat [FR]
			<sup>B</sup> 24.50	*93.95	38.80	<sup>a</sup> Diprosone [MK]

### betamethasone (as dipropionate) 0.05% ointment, 15 g

10823P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*69.45	38.80	<sup>a</sup> Elephrat [FR]
			<sup>B</sup> 24.50	*93.95	38.80	<sup>a</sup> Diprosone [MK]

## ■ BETAMETHASONE VALERATE

### Restricted benefit

Corticosteroid-responsive dermatoses

### betamethasone (as valerate) 0.02% cream, 100 g

2812B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*26.57	27.78	<sup>a</sup> Antroquoril [FR]
						<sup>b</sup> Cortival 1/5 [FM]
			<sup>B</sup> 5.00	*31.57	27.78	<sup>a</sup> Celestone-M [MK]
			<sup>B</sup> 5.98	*32.55	27.78	<sup>b</sup> Betnovate 1/5 [QA]

## ■ BETAMETHASONE VALERATE

### Note Continuing Therapy Only:

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

#### Restricted benefit

Corticosteroid-responsive dermatoses

### betamethasone (as valerate) 0.05% cream, 15 g

2813C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	12.82	14.03	<sup>a</sup> Cortival 1/2 [FM]
			<sup>B</sup> 2.56	15.38	14.03	<sup>a</sup> Betnovate 1/2 [QA]

## ■ BETAMETHASONE VALERATE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6232**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10799J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*14.55	15.76	<sup>a</sup> Cortival 1/2 [FM]
			<sup>B</sup> 5.12	*19.67	15.76	<sup>a</sup> Betnovate 1/2 [QA]

▪ **BETAMETHASONE VALERATE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6246**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10794D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*18.03	19.24	<sup>a</sup> Cortival 1/2 [FM]
			<sup>B</sup> 10.24	*28.27	19.24	<sup>a</sup> Betnovate 1/2 [QA]

▪ **BETAMETHASONE VALERATE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10808W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*21.49	22.70	<sup>a</sup> Cortival 1/2 [FM]
			<sup>B</sup> 15.36	*36.85	22.70	<sup>a</sup> Betnovate 1/2 [QA]

▪ **BETAMETHASONE VALERATE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10807T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*24.91	26.12	<sup>a</sup> Cortival 1/2 [FM]
			<sup>B</sup> 20.48	*45.39	26.12	<sup>a</sup> Betnovate 1/2 [QA]

▪ **BETAMETHASONE VALERATE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6231**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10810Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	10	5	..	*28.35	29.56	<sup>a</sup> Cortival 1/2 [FM]
			<sup>B</sup> 25.60	*53.95	29.56	<sup>a</sup> Betnovate 1/2 [QA]

**■ METHYLPREDNISOLONE****Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**methyprednisolone aceponate 0.1% cream, 15 g**

8054X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.66	18.87	Advantan [BN]

**methyprednisolone aceponate 0.1% ointment, 15 g**

8055Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.66	18.87	Advantan [BN]

**methyprednisolone aceponate 0.1% ointment: fatty, 15 g**

8128T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.66	18.87	Advantan [BN]

**■ METHYLPREDNISOLONE****Note Continuing Therapy Only:**

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

**Restricted benefit**

Eczema

**methyprednisolone aceponate 0.1% lotion, 20 g**

8618N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	18.25	19.46	Advantan [BN]

**■ METHYLPREDNISOLONE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6232**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**methyprednisolone aceponate 0.1% cream, 15 g**

10842P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.23	25.44	Advantan [BN]

**methyprednisolone aceponate 0.1% lotion, 20 g**

10856J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*25.41	26.62	Advantan [BN]

**methyprednisolone aceponate 0.1% ointment, 15 g**

10846W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.23	25.44	Advantan [BN]

**methyprednisolone aceponate 0.1% ointment: fatty, 15 g**

10848Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.23	25.44	Advantan [BN]

## ■ METHYLPREDNISOLONE

### Note Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**6246**

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

### methylprednisolone aceponate 0.1% cream, 15 g

10855H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*37.39	38.60	Advantan [BN]

### methylprednisolone aceponate 0.1% lotion, 20 g

10838K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*32.56	33.77	Advantan [BN]

### methylprednisolone aceponate 0.1% ointment, 15 g

10836H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*37.39	38.60	Advantan [BN]

### methylprednisolone aceponate 0.1% ointment: fatty, 15 g

10840M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*37.39	38.60	Advantan [BN]

## ■ METHYLPREDNISOLONE

### Note Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**6231**

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

### methylprednisolone aceponate 0.1% cream, 15 g

10833E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*76.75	38.80	Advantan [BN]

### methylprednisolone aceponate 0.1% lotion, 20 g

10830B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*46.90	38.80	Advantan [BN]

### methylprednisolone aceponate 0.1% ointment, 15 g

10845T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*76.75	38.80	Advantan [BN]

### methylprednisolone aceponate 0.1% ointment: fatty, 15 g

10843Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*76.75	38.80	Advantan [BN]

## ■ METHYLPREDNISOLONE

### Note Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**6218**

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

10835G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*50.53	38.80	Advantan [BN]

**methylprednisolone aceponate 0.1% ointment, 15 g**

10853F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*50.53	38.80	Advantan [BN]

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

10844R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*50.53	38.80	Advantan [BN]

**■ METHYLPREDNISOLONE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

10851D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*63.63	38.80	Advantan [BN]

**methylprednisolone aceponate 0.1% ointment, 15 g**

10834F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*63.63	38.80	Advantan [BN]

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

10839L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*63.63	38.80	Advantan [BN]

**■ METHYLPREDNISOLONE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**Authority required (STREAMLINED)****6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**methylprednisolone aceponate 0.1% lotion, 20 g**

10852E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*39.75	38.80	Advantan [BN]

**■ MOMETASONE****Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**mometasone furoate 0.1% cream, 15 g**

1913Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.40	15.61	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]

<sup>B</sup>3.53 17.93 15.61 <sup>a</sup> Elocon Alcohol Free [MK]

### mometasone furoate 0.1% lotion, 30 mL

8043H	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	16.32	17.53	<sup>a</sup> Momasone [QA] <sup>a</sup> Zatamil [EO]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 3.53	19.85	17.53	<sup>a</sup> Elocon [MK]	

### mometasone furoate 0.1% ointment, 15 g

1915T	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	14.40	15.61	<sup>a</sup> Momasone [QA] <sup>a</sup> Zatamil [EO]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 3.53	17.93	15.61	<sup>a</sup> Elocon [MK]	

## ■ MOMETASONE

### Note Continuing Therapy Only:

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### Authority required (STREAMLINED)

#### 6232

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

### mometasone furoate 0.1% cream, 15 g

10827W	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*17.71	18.92	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 7.06	*24.77	18.92	<sup>a</sup> Elocon Alcohol Free [MK]	

### mometasone furoate 0.1% lotion, 30 mL

10819K	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*21.55	22.76	<sup>a</sup> Momasone [QA] <sup>a</sup> Zatamil [EO]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 7.06	*28.61	22.76	<sup>a</sup> Elocon [MK]	

### mometasone furoate 0.1% ointment, 15 g

10812C	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*17.71	18.92	<sup>a</sup> Momasone [QA] <sup>a</sup> Zatamil [EO]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 7.06	*24.77	18.92	<sup>a</sup> Elocon [MK]	

## ■ MOMETASONE

### Note Continuing Therapy Only:

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### Authority required (STREAMLINED)

#### 6246

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

### mometasone furoate 0.1% cream, 15 g

10809X	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*24.35	25.56	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 14.12	*38.47	25.56	<sup>a</sup> Elocon Alcohol Free [MK]	

### mometasone furoate 0.1% lotion, 30 mL

10826T	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*26.77	27.98	<sup>a</sup> Momasone [QA] <sup>a</sup> Zatamil [EO]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 10.59	*37.36	27.98	<sup>a</sup> Elocon [MK]	

### mometasone furoate 0.1% ointment, 15 g

10814E	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*24.35	25.56	<sup>a</sup> Momasone [QA] <sup>a</sup> Zatamil [EO]	<sup>a</sup> Novasone [AF]

<sup>B</sup>14.12 \*38.47 25.56 <sup>a</sup> Elocon [MK]

## ■ MOMETASONE

### Note Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**6218**

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

### mometasone furoate 0.1% cream, 15 g

10815F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*30.97	32.18	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 21.18	*52.15	32.18	<sup>a</sup> Elocon Alcohol Free [MK]	

### mometasone furoate 0.1% ointment, 15 g

10828X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*30.97	32.18	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 21.18	*52.15	32.18	<sup>a</sup> Zatamil [EO]	<sup>a</sup> Elocon [MK]

## ■ MOMETASONE

### Note Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**6263**

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

### mometasone furoate 0.1% cream, 15 g

10818J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*37.55	38.76	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 28.24	*65.79	38.76	<sup>a</sup> Elocon Alcohol Free [MK]	

### mometasone furoate 0.1% ointment, 15 g

10793C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*37.55	38.76	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 28.24	*65.79	38.76	<sup>a</sup> Zatamil [EO]	<sup>a</sup> Elocon [MK]

## ■ MOMETASONE

### Note Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**6231**

Corticosteroid-responsive dermatoses

#### Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

### mometasone furoate 0.1% cream, 15 g

10792B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*44.15	38.80	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 35.30	*79.45	38.80	<sup>a</sup> Elocon Alcohol Free [MK]	

### mometasone furoate 0.1% lotion, 30 mL

10804P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	5	..	*37.25	38.46	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 17.65	*54.90	38.46	<sup>a</sup> Zatamil [EO]	<sup>a</sup> Elocon [MK]

**mometasone furoate 0.1% ointment, 15 g**

10791Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*44.15	38.80	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
						<sup>a</sup> Zatamil [EO]	
			<sup>B</sup> 35.30	*79.45	38.80	<sup>a</sup> Elocon [MK]	

**■ MOMETASONE****Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**Authority required (STREAMLINED)****6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**mometasone furoate 0.1% lotion, 30 mL**

10805Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*32.03	33.24	<sup>a</sup> Momasone [QA]	<sup>a</sup> Novasone [AF]
						<sup>a</sup> Zatamil [EO]	
			<sup>B</sup> 14.12	*46.15	33.24	<sup>a</sup> Elocon [MK]	

*Corticosteroids, very potent (group IV)***■ CLOBETASOL****Authority required (STREAMLINED)****5461**

Moderate to severe scalp psoriasis

**Clinical criteria:**

- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

**Population criteria:**

- Patient must be aged 18 years or older.

**clobetasol propionate 0.05% shampoo, 125 mL**

10080M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	48.81	38.80	Clobex [GA]

**■ ANTI-ACNE PREPARATIONS****ANTI-ACNE PREPARATIONS FOR TOPICAL USE***Retinoids for topical use in acne***■ ADAPALENE + BENZOYL PEROXIDE****Restricted benefit**

Severe acne vulgaris

Treatment Phase: Acute treatment

**Clinical criteria:**

- The treatment must in combination with an oral antibiotic.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

8954G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	36.29	37.50	Epiduo [GA]

**■ ADAPALENE + BENZOYL PEROXIDE****Note Continuing Therapy Only:**

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

**Restricted benefit**

Severe acne vulgaris

**Clinical criteria:**

- The treatment must be maintenance therapy.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

8955H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	36.29	37.50	Epiduo [GA]

**ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE***Retinoids for treatment of acne***ISOTRETINOIN**

**Caution** This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)****5224**

Severe cystic acne

**Clinical criteria:**

- The condition must be unresponsive to other therapy.

**isotretinoin 20 mg capsule, 60**

2592K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	47.99	38.80	<sup>a</sup> APO-Isotretinoin [TX] <sup>a</sup> Isotretinoin AN [EA] <sup>a</sup> Oratane [RF] <sup>a</sup> Rocta 20 [RW]	<sup>a</sup> Dermatane [ER] <sup>a</sup> Isotretinoin SCP 20 [CR] <sup>a</sup> Roaccutane [RO]

**isotretinoin 40 mg capsule, 30**

2549E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	44.40	38.80	<sup>a</sup> Dermatane [ER]	<sup>a</sup> Oratane [RF]

**isotretinoin 10 mg capsule, 60**

2591J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	34.77	35.98	<sup>a</sup> APO-Isotretinoin [TX] <sup>a</sup> Isotretinoin AN [EA] <sup>a</sup> Rocta 10 [RW]	<sup>a</sup> Dermatane [ER] <sup>a</sup> Oratane [RF]

**OTHER DERMATOLOGICAL PREPARATIONS****OTHER DERMATOLOGICAL PREPARATIONS***Agents for dermatitis, excluding corticosteroids***PIMECROLIMUS**

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

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

**Authority required (STREAMLINED)****5482**

Atopic dermatitis

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

**Authority required (STREAMLINED)****5472**

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**

- The condition must have been initially diagnosed more than three months prior to this treatment, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period. Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:
  - (i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
  - (ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
  - (iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
  - (iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

**pimecrolimus 1% cream, 15 g**

8802G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	33.70	34.91	Elidel [HM]

*Other dermatologicals*
**▪ DAPSONE**
**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**dapsone 25 mg tablet, 100**

8801F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	288.57	38.80	Link Medical Products Pty Ltd [LM]

**dapsone 100 mg tablet, 100**

1272Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	353.02	38.80	Link Medical Products Pty Ltd [LM]

**▪ IMIQUIMOD**

**Note** The patient or carer must be able to understand and administer the imiquimod dosing regimen.

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

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

**Note** Treatment of recurrent (previously treated) lesions will not be authorised.

**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

**Authority required**

Superficial basal cell carcinoma

**Clinical criteria:**

- The condition must be previously untreated, **AND**
- The condition must be confirmed by biopsy, **AND**
- Patient must have normal immune function, **AND**
- The condition must not be suitable for treatment with surgical excision; OR
- The condition must not be suitable for treatment with cryotherapy; OR
- The condition must not be suitable for treatment with curettage with diathermy, **AND**
- Patient must require topical drug therapy.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

**imiquimod 5% cream, 2 x 2 g**

2637T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	<sup>B</sup> 4.55	91.17	38.80	<sup>a</sup> Aldara Pump [IA]

**imiquimod 5% cream, 12 x 250 mg sachets**

2546B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	86.62	38.80	<sup>a</sup> Aldiq [QA]	<sup>a</sup> APO-Imiquimod [TX]
			<sup>B</sup> 2.28	88.90	38.80	<sup>a</sup> Aldara [IA]	

**▪ GENITO URINARY SYSTEM AND SEX HORMONES**
**▪ OTHER GYNECOLOGICALS**
**CONTRACEPTIVES FOR TOPICAL USE**
*Intrauterine contraceptives*

▪ **LEVONORGESTREL**

**Restricted benefit**

Contraception

**Restricted benefit**

Idiopathic menorrhagia

**Clinical criteria:**

- The treatment must be in a patient where oral treatments are ineffective.

**Restricted benefit**

Idiopathic menorrhagia

**Clinical criteria:**

- The treatment must be in a patient where oral treatments are contraindicated.

**levonorgestrel 52 mg intrauterine drug delivery system, 1 system**

8633J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	242.55	38.80	Mirena [BN]

**OTHER GYNECOLOGICALS**

*Prolactine inhibitors*

▪ **BROMOCRIPTINE**

**Restricted benefit**

Prevention of the onset of lactation

**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**bromocriptine 2.5 mg tablet, 30**

1444B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	21.96	23.17	Parlodel [SZ]

▪ **BROMOCRIPTINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson disease

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

1443Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*32.83	34.04	Parlodel [SZ]

▪ **CABERGOLINE**

**Restricted benefit**

Prevention of the onset of lactation

**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**cabergoline 500 microgram tablet, 2**

8115D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	24.45	25.66	<sup>a</sup> APO-Cabergoline [TX]	<sup>a</sup> Dostinex [PF]

▪ **CABERGOLINE**

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**cabergoline 500 microgram tablet, 8**

8114C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	64.55	38.80	<sup>a</sup> APO-Cabergoline [TX]	<sup>a</sup> Dostinex [PF]

▪ **QUINAGOLIDE**

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6**

8860H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.26	16.47	Norprolac [FP]

**quinagolide 75 microgram tablet, 30**

8822H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	52.76	38.80	Norprolac [FP]

▪ **SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM**

**HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE**

*Progestogens and estrogens, fixed combinations*

▪ **LEVONORGESTREL + ETHINYLOESTRADIOL**

**levonorgestrel 125 microgram + ethinylloestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

1456P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	18.81	20.02	Microgynon 50 ED [BN]

**ethinylloestradiol 20 microgram + levonorgestrel 100 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]**

2416E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.20	18.41	Femme-Tab ED 20/100 [AE]

**levonorgestrel 150 microgram + ethinylloestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

1394J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.20	18.41	<sup>a</sup> Monofeme 28 [FZ]	
						<sup>b</sup> Eleanor 150/30 ED [EA]	<sup>b</sup> Evelyn 150/30 ED [GQ]
						<sup>b</sup> Femme-Tab ED 30/150 [AE]	<sup>b</sup> Lenest 30 ED [AF]
						<sup>b</sup> Micronelle 30 ED [TX]	
			<sup>B</sup> 3.25	20.45	18.41	<sup>b</sup> Levlen ED [SY]	
			<sup>B</sup> 9.02	26.22	18.41	<sup>b</sup> Microgynon 30 ED [BN]	
			<sup>B</sup> 11.56	28.76	18.41	<sup>a</sup> Nordette 28 [PF]	

**■ NORETHISTERONE + ETHINYLOESTRADIOL**

**norethisterone 1 mg + ethinylloestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

2775C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.82	21.03	<sup>a</sup> Norimin-1 28 Day [FZ]
			<sup>B</sup> 9.78	29.60	21.03	<sup>a</sup> Brevinor-1 [PF]

**norethisterone 500 microgram + ethinylloestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

2774B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.82	21.03	<sup>a</sup> Norimin 28 Day [FZ]
			<sup>B</sup> 9.78	29.60	21.03	<sup>a</sup> Brevinor [PF]

**■ NORETHISTERONE + MESTRANOL**

**norethisterone 1 mg + mestranol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

3179H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.82	21.03	Norinyl-1/28 [PF]

*Progestogens and estrogens, sequential preparations*

**■ LEVONORGESTREL + ETHINYLOESTRADIOL**

**ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28]**

1392G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18.81	20.02	<sup>a</sup> Trifeme 28 [FZ]
						<sup>b</sup> Logynon ED [SY]
			<sup>B</sup> 11.41	30.22	20.02	<sup>b</sup> Triquilar ED [BN]
			<sup>B</sup> 13.00	31.81	20.02	<sup>a</sup> Triphasil 28 [PF]

*Progestogens*

**■ ETONOGESTREL**

**etonogestrel 68 mg implant, 1**

8487Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	193.08	38.80	Implanon NXT [MK]

**■ LEVONORGESTREL**

**levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]**

2913H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	2	..	20.10	21.31	Microlut 28 [BN]

**■ MEDROXYPROGESTERONE**

**medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial**

3118D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	25.22	26.43	<sup>a</sup> Depo-Ralovera [FZ]
			<sup>B</sup> 7.00	32.22	26.43	<sup>a</sup> Depo-Provera [PF]

## ■ NORETHISTERONE

### norethisterone 350 microgram tablet, 4 x 28

1967M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	19.82	21.03	Noriday 28 Day [PF]

## ANDROGENS

### 3-oxoandrogen (4) derivatives

## ■ TESTOSTERONE

### Authority required

Androgen deficiency

### Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

### Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

### Authority required

Androgen deficiency

### Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

### Population criteria:

- Patient must be aged 40 years or older.

### Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

### Authority required

Micropenis

### Population criteria:

- Patient must be under 18 years of age.

### Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

### Authority required

Pubertal induction

### Population criteria:

- Patient must be under 18 years of age.

### Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

### Authority required

Constitutional delay of growth or puberty

### Population criteria:

- Patient must be under 18 years of age.

### Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone 5% (50 mg/mL) cream, 50 mL**

10378F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	6	..	73.95	38.80	AndroForte 5 [LX]

**testosterone 2.5 mg/24 hours patch, 60**

8460G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	88.31	38.80	Androderm [GN]

**testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets**

8830R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	87.70	38.80	Testogel [HB]

**testosterone 5 mg/24 hours patch, 30**

8619P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	88.31	38.80	Androderm [GN]

**testosterone 2% (30 mg/actuation) solution, 60 actuations**

2341F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	76.76	38.80	Axiron [LY]

**testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations**

10380H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	4	..	87.70	38.80	Testogel [HB]

**■ TESTOSTERONE ENANTHATE**
**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes**

2114G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	33.44	34.65	Primoteston Depot [BN]

**■ TESTOSTERONE UNDECANOATE**
**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone undecanoate 40 mg capsule, 60**

2115H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	36.79	38.00	Andriol Testocaps [MK]

**testosterone undecanoate 1 g/4 mL injection, 4 mL vial**

10205D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	132.86	38.80	Reandron 1000 [BN]

**ESTROGENS**

*Natural and semisynthetic estrogens, plain*

▪ **OESTRADIOL**

**Note Continuing Therapy Only:**

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

**oestradiol 10 microgram modified release pessary, 18**

10203B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	33.16	34.37	Vagifem Low [NO]

**oestradiol valerate 1 mg tablet, 56**

1663M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	15.66	16.87	Progynova [BN]

**oestradiol 2 mg tablet, 56**

8274L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.29	18.50	Zumenon [GO]

**oestradiol valerate 2 mg tablet, 56**

1664N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.59	18.80	Progynova [BN]

▪ **OESTRADIOL**

**Note** Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

**Note Continuing Therapy Only:**

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

**oestradiol 100 microgram/24 hours patch, 4**

8126Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	22.14	23.35	Climara 100 [BN]

**oestradiol 75 microgram/24 hours patch, 8**

8764G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	22.14	23.35	Estradot 75 [SZ]

**oestradiol 75 microgram/24 hours patch, 4**

8486P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	22.14	23.35	Climara 75 [BN]

**oestradiol 25 microgram/24 hours patch, 4**

8485N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	20.37	21.58	Climara 25 [BN]

**oestradiol 50 microgram/24 hours patch, 8**

8140K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.37	21.58	Estraderm MX 50 [JU]

**oestradiol 50 microgram/24 hours patch, 8**

8763F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.37	21.58	Estradot 50 [SZ]

**oestradiol 37.5 microgram/24 hours patch, 8**

8762E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.37	21.58	Estradot 37.5 [SZ]

**oestradiol 25 microgram/24 hours patch, 8**

8311K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.37	21.58	Estraderm MX 25 [JU]

**oestradiol 25 microgram/24 hours patch, 8**

8761D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.37	21.58	Estradot 25 [SZ]

**oestradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

8286D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.37	21.58	Sandrena [AS]

**oestradiol 50 microgram/24 hours patch, 4**

8125P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.37	21.58	Climara 50 [BN]

**oestradiol 100 microgram/24 hours patch, 8**

8312L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	22.14	23.35	Estraderm MX 100 [JU]

**oestradiol 100 microgram/24 hours patch, 8**

8765H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	22.14	23.35	Estradot 100 [SZ]

▪ **OESTRIOL**

**Note Continuing Therapy Only:**

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

**oestriol 0.1% (1 mg/g) cream, 15 g**

1781R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	21.56	22.77	Ovestin [AS]

**oestriol 500 microgram pessary, 15**

1771F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	23.35	24.56	Ovestin Ovula [AS]

**PROGESTOGENS**

*Pregnen (4) derivatives*

▪ **MEDROXYPROGESTERONE**

**Note Continuing Therapy Only:**

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

**medroxyprogesterone acetate 5 mg tablet, 56**

2323G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.09	20.30	<sup>a</sup> Ralovera [FZ]
			<sup>B</sup> 6.70	25.79	20.30	<sup>a</sup> Provera [PF]

**medroxyprogesterone acetate 10 mg tablet, 30**

2321E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.96	19.17	<sup>a</sup> Ralovera [FZ]
			<sup>b</sup> 6.70	24.66	19.17	<sup>a</sup> Provera [PF]

▪ **MEDROXYPROGESTERONE**

Restricted benefit

Endometriosis

**medroxyprogesterone acetate 10 mg tablet, 100**

2722G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	33.99	35.20	<sup>a</sup> Ralovera [FZ]
			<sup>b</sup> 6.70	40.69	35.20	<sup>a</sup> Provera [PF]

*Estren derivatives*

▪ **NORETHISTERONE**

**Note Continuing Therapy Only:**

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

**norethisterone 5 mg tablet, 30**

2993M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	33.30	34.51	Primolut N [BN]

**PROGESTOGENS AND ESTROGENS IN COMBINATION**

*Progestogens and estrogens, fixed combinations*

▪ **OESTRADIOL + DYDROGESTERONE**

**Note Continuing Therapy Only:**

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

**oestradiol 1 mg + dydrogesterone 5 mg tablet, 28**

10142T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	21.82	23.03	Femoston-Conti [GO]

▪ **OESTRADIOL + NORETHISTERONE ACETATE**

**Note Continuing Therapy Only:**

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

**oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

8428N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	22.14	23.35	Estalis continuous 50/250 [SZ]

**oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

8427M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	22.14	23.35	Estalis continuous 50/140 [SZ]

*Progestogens and estrogens, sequential preparations*

▪ **NORETHISTERONE ACETATE + OESTRADIOL (&) OESTRADIOL**

**Note Continuing Therapy Only:**

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

**oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 1 pack**

8426L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	22.14	23.35	Estalis sequi 50/250 [SZ]

**oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 1 pack**

8245K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.14	23.35	Estalis sequi 50/140 [SZ]

**▪ OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE**
**Note Continuing Therapy Only:**

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

**oestradiol 2 mg tablet [14] (&) oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 1 pack**

8244X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	21.82	23.03	Femoston 2/10 [GO]

**oestradiol 1 mg tablet [14] (&) oestradiol 1 mg + dydrogesterone 10 mg tablet [14], 1 pack**

10146B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	21.82	23.03	Femoston 1/10 [GO]

**GONADOTROPINS AND OTHER OVULATION STIMULANTS**
*Gonadotropins*
**▪ FOLLITROPIN ALFA**

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge**

8715Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*733.65	38.80	Gonal-f Pen [SG]

**follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices**

10876K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*1348.21	38.80	Bemfola [FX]

**follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices**

10865W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*460.33	38.80	Bemfola [FX]

**follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge**

8713N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*369.22	38.80	Gonal-f Pen [SG]

**follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge**

8714P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*551.44	38.80	Gonal-f Pen [SG]

**follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices**

10877L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*915.85	38.80	Bemfola [FX]

**▪ FOLLITROPIN BETA**

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge**

8871X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*924.87	38.80	Puregon 900 IU/1.08 mL [MK]

**follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge**

8565T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*480.55	38.80	Puregon 300 IU/0.36 mL [MK]

**follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge**

8566W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*623.69	38.80	Puregon 600 IU/0.72 mL [MK]

**▪ HUMAN CHORIONIC GONADOTROPHIN**

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism.

**Restricted benefit**

Infertility

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be associated with isolated luteinising hormone deficiency.

**Restricted benefit**

Combined deficiency of human growth hormone and gonadotrophins

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

**Restricted benefit**

Hypogonadism or delayed puberty

**Population criteria:**

- Patient must be male, **AND**
- Patient must be aged 16 years or older.

**Clinical criteria:**

- Patient must show clinical evidence of the condition, **AND**

- The treatment must not extend beyond 6 months.

**human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

11148R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	45.04	38.80	Pregnyl [MK]

*Ovulation stimulants, synthetic*

▪ **CLOMIFENE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Restricted benefit**

Anovulatory infertility

**Restricted benefit**

Patients undergoing in-vitro fertilisation

**clomifene citrate 50 mg tablet, 10**

1211R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	35.52	36.73	Clomid [SW]

**ANTIANDROGENS**

*Antiandrogens, plain*

▪ **CYPROTERONE**

**cyproterone acetate 100 mg tablet, 50**

8019C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	66.87	38.80	<sup>a</sup> ANTERONE 100 [RW] <sup>a</sup> Cyprone 100 [AF] <sup>a</sup> Cyproterone AN [EA] <sup>a</sup> GenRx Cyproterone Acetate [GX]	<sup>a</sup> Cyprocur 100 [QA] <sup>a</sup> Cyprostat-100 [SY] <sup>a</sup> Cyproterone Sandoz [HX] <sup>a</sup> Procur 100 [ED]
			<sup>B</sup> 1.41	68.28	38.80	<sup>a</sup> Androcur-100 [BN]	

**cyproterone acetate 50 mg tablet, 50**

1270W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*82.69	38.80	<sup>a</sup> ANTERONE 50 [RW] <sup>a</sup> Cyprone [AF] <sup>a</sup> Cyproterone AN [EA] <sup>a</sup> Cyrotone [ER]	<sup>a</sup> Cyprocur 50 [QA] <sup>a</sup> Cyprostat [SY] <sup>a</sup> Cyproterone Sandoz [HX] <sup>a</sup> GenRx Cyproterone Acetate [GX]
			<sup>B</sup> 2.28	*84.97	38.80	<sup>a</sup> Androcur [BN]	

▪ **CYPROTERONE**

**Caution** This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

**Authority required (STREAMLINED)**

**5532**

Moderate to severe androgenisation

**Clinical criteria:**

- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

**Population criteria:**

- Patient must be female.

**Clinical criteria:**

- Patient must not be pregnant.

**cyproterone acetate 50 mg tablet, 20**

1269T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	25.41	26.62	<sup>a</sup> ANTERONE 50 [RW] <sup>a</sup> Cyprone [AF] <sup>a</sup> Cyproterone AN [EA] <sup>a</sup> GenRx Cyproterone Acetate [GX]	<sup>a</sup> Cyprocur 50 [QA] <sup>a</sup> Cyprostat [SY] <sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 2.40	27.81	26.62	<sup>a</sup> Androcur [BN]	

**OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM**

*Antigonadotropins and similar agents*

▪ **DANAZOL**

**Caution** Pregnancy must be excluded prior to administration of this drug.

**Authority required (STREAMLINED)**

**6293**

Endometriosis

**Clinical criteria:**

- The condition must be visually proven.

**Authority required (STREAMLINED)**

**6285**

Hereditary angio-oedema

**Authority required (STREAMLINED)**

**6259**

Intractable primary menorrhagia

**Clinical criteria:**

- The treatment must be for the short-term (up to 6 months).

**Note** Treatment of this indication is limited to 6 months. See Australian Product Information

**Authority required (STREAMLINED)**

**6242**

Breast disease

**Clinical criteria:**

- The treatment must be for the short-term (up to 6 months), **AND**
- The condition must be severe benign (fibrocystic) breast disease; OR
- The condition must be mastalgia associated with severe symptomatic benign breast disease, **AND**
- The condition must be refractory to treatment with other drugs.

**Note** Treatment of this indication is limited to 6 months. See Australian Product Information

**danazol 100 mg capsule, 100**

1285P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	56.14	38.80	Azol 100 [AF]

**danazol 200 mg capsule, 100**

1287R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	80.66	38.80	Azol 200 [AF]

*Progesterone receptor modulators*

▪ **MIFEPRISTONE (&) MISOPROSTOL**

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

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

**Authority required**

Termination of an intra-uterine pregnancy

**Clinical criteria:**

- The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

**Treatment criteria:**

- Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

**mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack**

10211K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	311.79	38.80	MS-2 Step [XH]

▪ **UROLOGICALS**

**UROLOGICALS**

*Drugs for urinary frequency and incontinence*

▪ **OXYBUTYNIN**

**Restricted benefit**

Detrusor overactivity

**oxybutynin hydrochloride 5 mg tablet, 100**

8039D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	14.90	16.11	<sup>a</sup> Ditropan [SW]	<sup>a</sup> Oxybutynin Sandoz [SZ]

▪ **OXYBUTYNIN**

**Restricted benefit**

Detrusor overactivity

**Clinical criteria:**

- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.

**oxybutynin 3.9 mg/24 hours patch, 8**

9454N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	36.14	37.35	Oxytrol [GN]

▪ **PROPANTHELINE**

**Restricted benefit**

Detrusor overactivity

**proprantheline bromide 15 mg tablet, 100**

1953T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*27.65	28.86	Pro-Banthine [RW]

*Other urologicals*

▪ **BICARBONATE**

**sodium bicarbonate 840 mg capsule, 100**

9470K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.28	20.49	Sodibic [AS]

▪ **PHENOXYBENZAMINE**

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Phaeochromocytoma

**Restricted benefit**

Neurogenic urinary retention

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

1862B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1103.27	38.80	Dibenyline [GH]

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

9286R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1103.27	38.80	Dibenzyline [BZ]

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

1166J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*997.75	38.80	Amdipharm Mercury (Australia) Pty Limited [GH]

**DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY**

*Alpha-adrenoreceptor antagonists*

▪ **DUTASTERIDE + TAMSULOSIN**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6189**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

5490Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	31.97	33.18	Duodart 500ug/400ug [GK]

*Testosterone-5-alpha reductase inhibitors*

▪ **DUTASTERIDE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6202**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

**dutasteride 500 microgram capsule, 30**

5468T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	27.76	28.97	<sup>a</sup> APO-Dutasteride [TX]	<sup>a</sup> Avodart [GK]

■ **SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

■ **PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES**

**ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES**

*ACTH*

■ **TETRACOSACTRIN**

**tetracosactrin 1 mg/mL modified release injection, 1 mL ampoule**

2832C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*449.95	38.80	Synacthen Depot 1 mg/1 mL [LM]

*Thyrotropin*

■ **THYROTROPIN ALFA**

**Restricted benefit**

Ablation of thyroid remnant tissue

**Clinical criteria:**

- Patient must have undergone a thyroidectomy, **AND**
- The treatment must be in combination with radioactive iodine, **AND**
- Patient must not have a known metastatic disease.

**thyrotropin alfa 900 microgram injection, 2 vials**

2700D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1802.84	38.80	Thyrogen [GZ]

**POSTERIOR PITUITARY LOBE HORMONES**

*Vasopressin and analogues*

■ **DESMOPRESSIN**

**Authority required (STREAMLINED)**

**5266**

Cranial diabetes insipidus

**desmopressin acetate 200 microgram tablet, 30**

8662X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*160.90	38.80	Minirin [FP]

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

8711L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*144.61	38.80	Minirin Nasal Spray [FP]

**desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL**

2129C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*144.75	38.80	Minirin [FP]

■ **DESMOPRESSIN**

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

**Authority required (STREAMLINED)**

**5413**

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

**5295**

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin acetate 200 microgram tablet, 30**

8663Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	61.03	38.80	Minirin [FP]

▪ **DESMOPRESSIN**

**Caution** Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

**Note** Not to be used in preference to enuresis alarms.

**Authority required (STREAMLINED)**

**5342**

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

**5267**

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

8712M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	77.85	38.80	Minirin Nasal Spray [FP]

▪ **DESMOPRESSIN**

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

**Authority required (STREAMLINED)**

**5412**

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

**5226**

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin 120 microgram sublingual wafer, 30**

9398P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	66.73	38.80	Minirin Melt [FP]

**desmopressin 240 microgram sublingual wafer, 30**

8975J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	105.68	38.80	Minirin Melt [FP]

**HYPOTHALAMIC HORMONES**

*Gonadotropin-releasing hormones*

▪ **NAFARELIN**

Restricted benefit

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven.

Restricted benefit

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven, **AND**
  - The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
  - Patient must have had a recent bone density assessment.
- The date of the bone density assessment must be recorded in the patient's medical records.

**nafarelin 200 microgram/actuation nasal spray, 60 actuations**

2962X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	125.06	38.80	Synarel [PF]

▪ **CORTICOSTEROIDS FOR SYSTEMIC USE**

**CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN**

*Mineralocorticoids*

▪ **FLUDROCORTISONE ACETATE**

**Note Continuing Therapy Only:**

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

**fludrocortisone acetate 100 microgram tablet, 100**

1433K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*44.89	38.80	Florinef [QA]

*Glucocorticoids*

▪ **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

**betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules**

5034Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	27.25	28.46	Celestone Chronodose [MK]

▪ **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Alopecia areata

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**Restricted benefit**

Lichen simplex chronicus

**Restricted benefit**

Chronic discoid lupus erythematosus

**Restricted benefit**

Necrobiosis lipoidica

**Restricted benefit**

Uveitis

**betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules**

2694T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.25	28.46	Celestone Chronodose [MK]

▪ **CORTISONE**

**Note Continuing Therapy Only:**

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

**cortisone acetate 25 mg tablet, 60**

1247P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	23.55	24.76	Cortate [AS]

**cortisone acetate 5 mg tablet, 50**

1246N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	18.42	19.63	Cortate [AS]

▪ **DEXAMETHASONE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**DEXAMETHASONE Tablet 500 micrograms, 30**

1292B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	13.19	14.40	Dexamethsone [AS]

**DEXAMETHASONE Tablet 4 mg, 30**

2507Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	16.29	17.50	Dexamethsone [AS]

▪ **DEXAMETHASONE SODIUM PHOSPHATE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5**

1291Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	26.10	27.31	<sup>a</sup> Dexamethasone Mylan [AF]	<sup>a</sup> Hospira Pty Limited [PF]

**DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5**

2509C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.21	18.42	<sup>a</sup> Dexamethasone Mylan [AF]	<sup>a</sup> Hospira Pty Limited [PF]

▪ **HYDROCORTISONE**

**Note Continuing Therapy Only:**

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

**hydrocortisone 20 mg tablet, 60**

1500Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	31.73	32.94	Hysone 20 [AF]

**hydrocortisone 4 mg tablet, 50**

1499X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	25.55	26.76	Hysone 4 [AF]

■ **HYDROCORTISONE SODIUM SUCCINATE**

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

1501B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*20.89	22.10	Solu-Cortef [PF]

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

3096Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	19.85	21.06	Solu-Cortef [PF]

■ **HYDROCORTISONE SODIUM SUCCINATE**

Restricted benefit

For use in a hospital

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

1510L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	..	..	*40.51	38.80	Solu-Cortef [PF]

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

5118J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	6	..	..	*40.51	38.80	Solu-Cortef [PF]

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

1511M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	..	..	*63.67	38.80	Solu-Cortef [PF]

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

5119K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	6	..	..	*63.67	38.80	Solu-Cortef [PF]

■ **METHYLPREDNISOLONE**

**methylprednisolone Powder for injection 1 g (as sodium succinate), 1**

5264C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	43.59	38.80	<sup>a</sup> Methylpred [AL]	<sup>a</sup> Methylprednisolone Alphapharm [AF]
						<sup>a</sup> Solu-Medrol [PF]	

■ **METHYLPREDNISOLONE**

Restricted benefit

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials**

1928L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.47	23.68	<sup>a</sup> Depo-Nisolone [FZ]
			<sup>b</sup> 2.61	25.08	23.68	<sup>a</sup> Depo-Medrol [PF]

■ **METHYLPREDNISOLONE**

**Note** Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

**methylprednisolone 40 mg injection [5 vials] (& inert substance diluent [5 x 1 mL vials], 1 pack**

2981X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	26.52	27.73	<sup>a</sup> Solu-Medrol [PF]

**methylprednisolone Powder for injection 40 mg (as sodium succinate), 5**

5263B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.23	24.44	<sup>a</sup> Methylpred [AL]

▪ **METHYLPREDNISOLONE**

Restricted benefit

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials**

5148Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	22.47	23.68	<sup>a</sup> Depo-Nisolone [FZ]
			<sup>B</sup> 2.61	25.08	23.68	<sup>a</sup> Depo-Medrol [PF]

▪ **PREDNISOLONE**

**prednisolone 1 mg tablet, 100**

3152X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	13.65	14.86	<sup>a</sup> Predsolone [LN]
			<sup>B</sup> 1.00	14.65	14.86	<sup>a</sup> Panafcortelone [AS]

**prednisolone 5 mg tablet, 60**

1917X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	14.09	15.30	Panafcortelone [AS]	Solone [IA]

**prednisolone 25 mg tablet, 30**

1916W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	15.37	16.58	Panafcortelone [AS]	Solone [IA]

▪ **PREDNISOLONE SODIUM PHOSPHATE**

**prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL**

8285C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	18.29	19.50	<sup>a</sup> PredMix [LN]
			<sup>B</sup> 2.35	20.64	19.50	<sup>a</sup> Redipred [AS]

▪ **PREDNISONE**

**prednisone 5 mg tablet, 60**

1935W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	14.00	15.21	Panafcort [AS]	Sone [IA]

**prednisone 25 mg tablet, 30**

1936X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	15.43	16.64	Panafcort [AS]	Sone [IA]

**prednisone 1 mg tablet, 100**

1934T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	13.60	14.81	<sup>a</sup> Predsone [LN]
			<sup>B</sup> 1.00	14.60	14.81	<sup>a</sup> Panafcort [AS]

▪ **TRIAMCINOLONE**

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

5233K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	27.25	28.46	Kenacort-A10 [QA]

▪ **TRIAMCINOLONE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Alopecia areata

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**Restricted benefit**

Lichen simplex chronicus

**Restricted benefit**

Chronic discoid lupus erythematosus

**Restricted benefit**

Necrobiosis lipoidica

**Restricted benefit**

Psoriasis

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

2990J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	27.25	28.46	Kenacort-A10 [QA]

**THYROID THERAPY**

**THYROID PREPARATIONS**

*Thyroid hormones*

**LIOTHYRONINE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6382**

Thyroid cancer

**Authority required (STREAMLINED)**

**6410**

Hypothyroidism

**Clinical criteria:**

- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to thyroxine sodium; OR
- Patient must have documented resistance to thyroxine sodium.

**Authority required (STREAMLINED)**

**6475**

Hypothyroidism

**Clinical criteria:**

- The condition must be severe hypothyroidism, **AND**
- The treatment must be for initiation of therapy only.

**liothyronine sodium 20 microgram tablet, 100**

2318B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	77.69	38.80	Tertroxin [QA]

**THYROXINE**

**Note Continuing Therapy Only:**

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

**thyroxine sodium 50 microgram tablet, 200**

2174K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	25.83	27.04	<sup>a</sup> Eutroxsig [FM]
			<sup>B</sup> 1.91	27.74	27.04	<sup>a</sup> Oroxine [QA]

**thyroxine sodium 100 microgram tablet, 200**

2175L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	26.36	27.57	<sup>a</sup> Eutroxig [FM]
			<sup>B</sup> 1.92	28.28	27.57	<sup>a</sup> Oroxine [QA]

**thyroxine sodium 200 microgram tablet, 200**

2173J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	28.99	30.20	<sup>a</sup> Eutroxig [FM]
			<sup>B</sup> 1.93	30.92	30.20	<sup>a</sup> Oroxine [QA]

**thyroxine sodium 75 microgram tablet, 200**

9287T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	26.39	27.60	<sup>a</sup> Eutroxig [FM]
			<sup>B</sup> 1.98	28.37	27.60	<sup>a</sup> Oroxine [QA]

**ANTITHYROID PREPARATIONS**

*Thiouracils*

▪ **PROPYLTHIOURACIL**

**Note Continuing Therapy Only:**

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

**propylthiouracil 50 mg tablet, 100**

1955X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*47.89	38.80	PTU [PL]

*Sulfur-containing imidazole derivatives*

▪ **CARBIMAZOLE**

**Note Continuing Therapy Only:**

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

**carbimazole 5 mg tablet, 100**

1153Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*43.35	38.80	Carbimazol ARISTO [PQ]	Neo-Mercazole [GH]

▪ **PANCREATIC HORMONES**

**GLYCOGENOLYTIC HORMONES**

*Glycogenolytic hormones*

▪ **GLUCAGON HYDROCHLORIDE**

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

1449G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	50.97	38.80	Glucagen Hypokit [NO]

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

5105Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	50.97	38.80	Glucagen Hypokit [NO]

▪ **CALCIUM HOMEOSTASIS**

**PARATHYROID HORMONES AND ANALOGUES**

*Parathyroid hormones and analogues*

▪ **TERIPARATIDE**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised agent, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au).

**Authority required**

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 20 microgram injection, 2.4 mL cartridge**

9411H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	411.80	38.80	Forteo [LY]

**ANTI-PARATHYROID AGENTS**

*Calcitonin preparations*

▪ **SALCATONIN**

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Symptomatic Paget disease of bone

**Restricted benefit**

Hypercalcaemia

**Clinical criteria:**

- The treatment must be initiated in a hospital.

**salcatonin 100 units/mL injection, 5 x 1 mL ampoules**

2997R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*144.67	38.80	Miacalcic 100 [NV]

▪ **ANTIINFECTIVES FOR SYSTEMIC USE**

▪ **ANTIBACTERIALS FOR SYSTEMIC USE**

**TETRACYCLINES**

*Tetracyclines*

▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

**doxycycline 100 mg tablet, 7**

2709N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.55	13.76	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]	<sup>a</sup> Doxycycline AN [EA]

**doxycycline 100 mg tablet, 7**

3321T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	12.55	13.76	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]	<sup>a</sup> Doxycycline AN [EA]

**doxycycline 100 mg tablet, 7**

5082L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	12.55	13.76	<sup>a</sup> APO-Doxycycline [TX] <sup>a</sup> Doxycycline Sandoz [HX] <sup>a</sup> Terry White Chemists Doxycycline [TW]	<sup>a</sup> Chem mart Doxycycline [CH] <sup>a</sup> GenRx Doxycycline [GX]

**doxycycline 100 mg tablet, 7**

9105F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.55	13.76	<sup>a</sup> APO-Doxycycline [TX] <sup>a</sup> Doxycycline Sandoz [HX] <sup>a</sup> Terry White Chemists Doxycycline [TW]	<sup>a</sup> Chem mart Doxycycline [CH] <sup>a</sup> GenRx Doxycycline [GX]

**doxycycline 100 mg modified release capsule, 7**

2708M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	<sup>B</sup> 1.54	14.09	13.76	<sup>a</sup> Mayne Pharma Doxycycline [YT]	
			<sup>B</sup> 2.96	15.51	13.76	<sup>a</sup> Doryx [YN]	

**doxycycline 100 mg modified release capsule, 7**

3322W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	<sup>B</sup> 1.54	14.09	13.76	<sup>a</sup> Mayne Pharma Doxycycline [YT]	
			<sup>B</sup> 2.96	15.51	13.76	<sup>a</sup> Doryx [YN]	

▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

**Restricted benefit**

Urethritis

**doxycycline 100 mg tablet, 21**

10176N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	15.48	16.69	<sup>a</sup> Doxycycline AN [EA]	<sup>a</sup> Doxylin 100 [AF]

**doxycycline 100 mg tablet, 21**

1800R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	15.48	16.69	<sup>a</sup> APO-Doxycycline [TX]	<sup>a</sup> GenRx Doxycycline [GX]

**doxycycline 100 mg modified release capsule, 21**

2715X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	<sup>B</sup> 3.21	18.69	16.69	<sup>a</sup> Mayne Pharma Doxycycline [YT]	
			<sup>B</sup> 9.00	24.48	16.69	<sup>a</sup> Doryx [YN]	

**doxycycline 100 mg tablet, 7**

2714W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	3	..	..	*15.46	16.67	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]	<sup>a</sup> Doxycycline AN [EA]

# ANTIINFECTIVES FOR SYSTEMIC USE

General

## doxycycline 100 mg tablet, 7

9108J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	3	..	..	*15.46	16.67	<sup>a</sup> Chem mart Doxycycline [CH] <sup>a</sup> Terry White Chemists Doxycycline [TW]	<sup>a</sup> Doxycycline Sandoz [HX]

### ■ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

#### Restricted benefit

Severe acne

## doxycycline 100 mg tablet, 7

10779H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*16.95	18.16	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]	<sup>a</sup> Doxycycline AN [EA]

## doxycycline 100 mg tablet, 7

10781K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*16.95	18.16	<sup>a</sup> APO-Doxycycline [TX] <sup>a</sup> Doxycycline Sandoz [HX] <sup>a</sup> Terry White Chemists Doxycycline [TW]	<sup>a</sup> Chem mart Doxycycline [CH] <sup>a</sup> GenRx Doxycycline [GX]

## doxycycline 100 mg modified release capsule, 7

10777F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	<sup>B</sup> 6.16	*23.11	18.16	<sup>a</sup> Mayne Pharma Doxycycline [YT]	
			<sup>B</sup> 11.84	*28.79	18.16	<sup>a</sup> Doryx [YN]	

### ■ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

#### Restricted benefit

Pelvic inflammatory disease

## doxycycline 100 mg tablet, 7

2702F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	..	..	*16.95	18.16	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]	<sup>a</sup> Doxycycline AN [EA]

## doxycycline 100 mg tablet, 7

9107H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	..	..	*16.95	18.16	<sup>a</sup> APO-Doxycycline [TX] <sup>a</sup> Doxycycline Sandoz [HX] <sup>a</sup> Terry White Chemists Doxycycline [TW]	<sup>a</sup> Chem mart Doxycycline [CH] <sup>a</sup> GenRx Doxycycline [GX]

## doxycycline 100 mg modified release capsule, 7

2703G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	..	<sup>B</sup> 6.16	*23.11	18.16	<sup>a</sup> Mayne Pharma Doxycycline [YT]	
			<sup>B</sup> 11.84	*28.79	18.16	<sup>a</sup> Doryx [YN]	

### ■ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hydrochloride), doxycycline tablet 50 mg (as monohydrate) and doxycycline capsule: modified release 50 mg (as hydrochloride) are equivalent for the purposes of substitution.

#### Restricted benefit

Bronchiectasis

#### Population criteria:

- Patient must be aged 8 years or older.

#### Restricted benefit

Chronic bronchitis

#### Population criteria:

- Patient must be aged 8 years or older.

#### Restricted benefit

Severe acne

**doxycycline 50 mg tablet, 25**

2711Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.42	14.63	<sup>a</sup> Doxycycline AN [EA]	<sup>a</sup> Doxylin 50 [AF]

**doxycycline 50 mg tablet, 25**

9106G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.42	14.63	<sup>a</sup> APO-Doxycycline [TX] <sup>a</sup> Doxycycline Sandoz [HX] <sup>a</sup> GenRx Doxycycline [GX]	<sup>a</sup> Chem mart Doxycycline [CH] <sup>a</sup> Frakas [RW] <sup>a</sup> Terry White Chemists Doxycycline [TW]

**doxycycline 50 mg modified release capsule, 25**

2707L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	<sup>B</sup> 2.59	16.01	14.63	<sup>a</sup> Mayne Pharma Doxycycline [YT]
			<sup>B</sup> 5.01	18.43	14.63	<sup>a</sup> Doryx [YN]

▪ **MINOCYCLINE**

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

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

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

**Restricted benefit**

Severe acne

**Clinical criteria:**

- The condition must not be responding to other tetracyclines.

**minocycline 50 mg tablet, 60**

1616C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.59	19.80	<sup>a</sup> Akamin 50 [AF]
			<sup>B</sup> 1.65	20.24	19.80	<sup>a</sup> Minomycin-50 [QA]

**BETA-LACTAM ANTIBACTERIALS, PENICILLINS**

*Penicillins with extended spectrum*

▪ **AMOXYCILLIN**

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

1888J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	<sup>S</sup> 0.53	#18.03	19.07	Amoxil [AS]

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

3310F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	<sup>S</sup> 0.53	#18.03	19.07	Amoxil [AS]

**amoxicillin 500 mg capsule, 20**

1889K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	12.81	14.02	<sup>a</sup> Alphamox 500 [AF] <sup>a</sup> Amoxicillin generichealth 500 [GQ] <sup>a</sup> Amoxicillin Sandoz [SZ] <sup>a</sup> Cilamox [QA]	<sup>a</sup> Amoxicillin AN [EA] <sup>a</sup> Amoxicillin Ranbaxy [RA] <sup>a</sup> APO-Amoxicillin [TX] <sup>a</sup> Yomax 500 [DO]
			<sup>B</sup> 3.76	16.57	14.02	<sup>a</sup> Amoxil [AS]	

**amoxicillin 500 mg capsule, 20**

3300Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	12.81	14.02	<sup>a</sup> Alphamox 500 [AF] <sup>a</sup> Amoxicillin generichealth 500 [GQ] <sup>a</sup> Amoxicillin Sandoz [SZ] <sup>a</sup> Cilamox [QA]	<sup>a</sup> Amoxicillin AN [EA] <sup>a</sup> Amoxicillin Ranbaxy [RA] <sup>a</sup> APO-Amoxicillin [TX] <sup>a</sup> Yomax 500 [DO]
			<sup>B</sup> 3.76	16.57	14.02	<sup>a</sup> Amoxil [AS]	

**amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL**

5225B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#15.63	17.20	Maxamox [SZ]

# ANTIINFECTIVES FOR SYSTEMIC USE

General

## amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

8705E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#15.63	17.20	Maxamox [SZ]

## amoxicillin 250 mg capsule, 20

1884E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	12.49	13.70	<sup>a</sup> Alphamox 250 [AF] <sup>a</sup> Amoxicillin Ranbaxy [RA] <sup>a</sup> APO-Amoxicillin [TX] <sup>a</sup> Yomax 250 [DO]	<sup>a</sup> Amoxicillin AN [EA] <sup>a</sup> Amoxicillin Sandoz [SZ] <sup>a</sup> Cilamox [QA]
			<sup>b</sup> 3.49	15.98	13.70	<sup>a</sup> Amoxil [AS]	

## amoxicillin 250 mg capsule, 20

3301R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	12.49	13.70	<sup>a</sup> Alphamox 250 [AF] <sup>a</sup> Amoxicillin Ranbaxy [RA] <sup>a</sup> APO-Amoxicillin [TX] <sup>a</sup> Yomax 250 [DO]	<sup>a</sup> Amoxicillin AN [EA] <sup>a</sup> Amoxicillin Sandoz [SZ] <sup>a</sup> Cilamox [QA]
			<sup>b</sup> 3.49	15.98	13.70	<sup>a</sup> Amoxil [AS]	

## amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

1886G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#15.20	16.77	<sup>a</sup> Alphamox 125 [AF] <sup>a</sup> APO-Amoxicillin [TX]	<sup>a</sup> Amoxicillin Sandoz [SZ] <sup>a</sup> Ranmoxy [RA]
			<sup>b</sup> 3.46	#18.66	16.77	<sup>a</sup> Amoxil [AS]	

## amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

3302T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#15.20	16.77	<sup>a</sup> Alphamox 125 [AF] <sup>a</sup> APO-Amoxicillin [TX]	<sup>a</sup> Amoxicillin Sandoz [SZ] <sup>a</sup> Ranmoxy [RA]
			<sup>b</sup> 3.46	#18.66	16.77	<sup>a</sup> Amoxil [AS]	

## amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL

1887H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#15.53	17.10	<sup>a</sup> Alphamox 250 [AF] <sup>a</sup> APO-Amoxicillin [TX] <sup>a</sup> Ranmoxy [RA]	<sup>a</sup> Amoxicillin Sandoz [SZ] <sup>a</sup> Cilamox [QA]
			<sup>b</sup> 3.56	#19.09	17.10	<sup>a</sup> Amoxil Forte [AS]	

## amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL

3393N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#15.53	17.10	<sup>a</sup> Alphamox 250 [AF] <sup>a</sup> APO-Amoxicillin [TX] <sup>a</sup> Ranmoxy [RA]	<sup>a</sup> Amoxicillin Sandoz [SZ] <sup>a</sup> Cilamox [QA]
			<sup>b</sup> 3.56	#19.09	17.10	<sup>a</sup> Amoxil Forte [AS]	

### ■ AMOXYCILLIN

#### Restricted benefit

Chronic bronchitis

#### Clinical criteria:

- Patient must have acute exacerbations of the condition.

## amoxicillin 1 g tablet, 14

8581P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.67	13.88	<sup>a</sup> Amoxicillin Sandoz [BG]
			<sup>b</sup> 1.08	13.75	13.88	<sup>a</sup> Maxamox [SZ]

### ■ AMOXYCILLIN

#### Authority required

Infection suspected or proven to be due to a susceptible organism

#### Clinical criteria:

- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

## amoxicillin 100 mg/mL powder for oral liquid, 20 mL

9714G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#18.03	19.60	Amoxil [AS]

▪ **AMPICILLIN**

**ampicillin 500 mg injection, 5 vials**

2390T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	16.05	17.26	Austrapen [AL]

**ampicillin 500 mg injection, 5 vials**

3313J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.05	17.26	Austrapen [AL]

**ampicillin 1 g injection, 5 vials**

2977Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	17.23	18.44	<sup>a</sup> Ampicyn [AF]	<sup>a</sup> Austrapen [AL]

**ampicillin 1 g injection, 5 vials**

3314K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	17.23	18.44	<sup>a</sup> Ampicyn [AF]	<sup>a</sup> Austrapen [AL]

*Beta-lactamase sensitive penicillins*

▪ **BENZATHINE BENZYL PENICILLIN**

**BENZATHINE BENZYL PENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10**

2267H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	309.22	38.80	Bicillin L-A [PF]

**BENZATHINE BENZYL PENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10**

5027N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	309.22	38.80	Bicillin L-A [PF]

▪ **BENZYL PENICILLIN**

**benzylpenicillin 3 g injection, 1 vial**

2647H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	10	..	..	*97.95	38.80	BenPen [CS]

**benzylpenicillin 3 g injection, 1 vial**

3399X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	10	..	..	*97.95	38.80	BenPen [CS]

**benzylpenicillin 600 mg injection, 1 vial**

1775K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	10	1	..	*61.35	38.80	BenPen [CS]

**benzylpenicillin 600 mg injection, 1 vial**

3398W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	10	..	..	*61.35	38.80	BenPen [CS]

▪ **PHENOXYMETHYL PENICILLIN**

**phenoxymethylpenicillin 250 mg capsule, 50**

1789E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	15.21	16.42	Cilicaine VK [FM]	LPV [IA]

**phenoxymethylpenicillin 250 mg capsule, 50**

3363B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	15.21	16.42	Cilicaine VK [FM]	LPV [IA]

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

5024K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	2	..	..	*#20.56	22.13	Phenoxymethylpenicillin-AFT [AE]

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

8976K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*#20.56	22.13	Phenoxymethylpenicillin-AFT [AE]

# ANTIINFECTIVES FOR SYSTEMIC USE

General

## phenoxymethylpenicillin 250 mg tablet, 25

1787C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*15.35	16.56	Aspecillin VK [QA]

## phenoxymethylpenicillin 250 mg tablet, 25

3360W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*15.35	16.56	Aspecillin VK [QA]

## phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

5012T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*24.29	25.50	Cilicaine V [FM]

## phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

9143F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*24.29	25.50	Cilicaine V [FM]

## phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

5029Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*#22.80	24.37	Phenoxymethylpenicillin-AFT [AE]

## phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

8977L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*#22.80	24.37	Phenoxymethylpenicillin-AFT [AE]

## phenoxymethylpenicillin 500 mg tablet, 25

3028J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*17.39	18.60	Aspecillin VK [QA]

## phenoxymethylpenicillin 500 mg tablet, 25

3361X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*17.39	18.60	Aspecillin VK [QA]

## phenoxymethylpenicillin 500 mg capsule, 50

2965C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.22	18.43	Cilicaine VK [FM]	LPV [IA]

## phenoxymethylpenicillin 500 mg capsule, 50

3364C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.22	18.43	Cilicaine VK [FM]	LPV [IA]

### ■ PHENOXYMETHYLPENICILLIN

#### Restricted benefit

Recurrent streptococcal infections (including rheumatic fever)

#### Clinical criteria:

- The treatment must be for prophylaxis.

## phenoxymethylpenicillin 250 mg capsule, 50

1705R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.21	16.42	Cilicaine VK [FM]	LPV [IA]

## phenoxymethylpenicillin 250 mg tablet, 25

1703P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*15.35	16.56	Aspecillin VK [QA]

### ■ PROCAINE PENICILLIN

## procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes

1794K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	85.18	38.80	Cilicaine [QA]

## procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes

3371K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	85.18	38.80	Cilicaine [QA]

*Beta-lactamase resistant penicillins*

▪ **DICLOXACILLIN**

**Restricted benefit**

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

5096F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.60	17.81	Distaph 250 [AF]

**dicloxacillin 500 mg capsule, 24**

5097G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	20.73	21.94	Distaph 500 [AF]

▪ **DICLOXACILLIN**

**Restricted benefit**

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

8121K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	16.60	17.81	Distaph 250 [AF]

**dicloxacillin 500 mg capsule, 24**

8122L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	20.73	21.94	Distaph 500 [AF]

▪ **DICLOXACILLIN**

**Authority required (STREAMLINED)**

**6188**

Osteomyelitis

**dicloxacillin 500 mg capsule, 24**

10790X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*30.37	31.58	Distaph 500 [AF]

▪ **FLUCLOXACILLIN**

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Note** Pharmaceutical benefits that have the form flucloxacillin 1 g injection in a pack size of 5 can be substituted for a pack size of 10 in the case of a shortage.

**flucloxacillin 1 g injection, 5 vials**

1525G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	19.67	20.88	<sup>a</sup> Flucil [AS]

**flucloxacillin 1 g injection, 5 vials**

5095E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	19.67	20.88	<sup>a</sup> Flucil [AS]

**flucloxacillin 1 g injection, 10 vials**

10605E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	0.5	1	..	*23.50	24.71	<sup>a</sup> Hospira Pty Limited [PF]

**flucloxacillin 1 g injection, 10 vials**

10609J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	0.5	..	..	*23.50	24.71	<sup>a</sup> Hospira Pty Limited [PF]

▪ **FLUCLOXACILLIN**

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

**flucloxacillin 500 mg capsule, 24**

1527J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	19.78	20.99	<sup>a</sup> APO-Flucloxacillin [TX]	<sup>a</sup> Flopen [AS]
						<sup>a</sup> Staphylex 500 [AF]	

## ANTIINFECTIVES FOR SYSTEMIC USE

### flucloxacillin 250 mg capsule, 24

1526H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	15.24	16.45	<sup>a</sup> APO-Flucloxacillin [TX] <sup>a</sup> Staphylex 250 [AF]	<sup>a</sup> Flopen [AS]

### FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

### flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL

5257Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#19.95	21.52	Flucil [LN]

### flucloxacillin 500 mg capsule, 24

5091Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	19.78	20.99	<sup>a</sup> APO-Flucloxacillin [TX] <sup>a</sup> Staphylex 500 [AF]	<sup>a</sup> Flopen [AS]

### flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL

5258R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#23.02	24.59	Flucil [LN]

### flucloxacillin 250 mg capsule, 24

5090X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	15.24	16.45	<sup>a</sup> APO-Flucloxacillin [TX] <sup>a</sup> Staphylex 250 [AF]	<sup>a</sup> Flopen [AS]

### FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

### flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL

9149M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#19.95	21.52	Flucil [LN]

### flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL

9150N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#23.02	24.59	Flucil [LN]

### FLUCLOXACILLIN

**Caution** Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Authority required (STREAMLINED)**

**6169**

Osteomyelitis

### flucloxacillin 500 mg capsule, 24

10788T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*28.47	29.68	<sup>a</sup> APO-Flucloxacillin [TX] <sup>a</sup> Staphylex 500 [AF]	<sup>a</sup> Flopen [AS]

### Combinations of penicillins, incl. beta-lactamase inhibitors

### AMOXYCILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

Infections where resistance to amoxicillin is proven

### amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL

8319W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#15.86	17.43	<sup>a</sup> APO-Amoxicillin and Clavulanic Acid 400/57 [TX]	<sup>a</sup> Curam Duo [SZ]
			<sup>B</sup> 4.84	#20.70	17.43	<sup>a</sup> Augmentin Duo 400 [AS]	

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

8254K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	13.86	15.07	<sup>a</sup> AlphaClav Duo Forte [AF]	<sup>a</sup> AMCLAVOX DUO FORTE 875/125 [RW]
						<sup>a</sup> AMOXICLAV AMNEAL 875/125 [ED]	<sup>a</sup> Amoxyclav AN 875/125 [EA]
						<sup>a</sup> AmoxyClav generichealth 875/125 [HQ]	<sup>a</sup> AmoxyClav GH 875/125 [GQ]
						<sup>a</sup> APO-Amoxicillin and Clavulanic Acid [TX]	<sup>a</sup> Chem mart Amoxicillin and Clavulanic Acid [CH]
						<sup>a</sup> Clavam 875 mg/125 mg [CR]	<sup>a</sup> Curam Duo Forte 875/125 [SZ]
						<sup>a</sup> Moxiclav Duo Forte 875/125 [QA]	<sup>a</sup> Terry White Chemists Amoxicillin and Clavulanic Acid [TW]
			<sup>B</sup> 6.24	20.10	15.07	<sup>a</sup> Augmentin Duo forte [AS]	

**amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10**

1891M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	1	..	13.56	14.77	<sup>a</sup> AlphaClav Duo [AF]	<sup>a</sup> AMCLAVOX DUO 500/125 [RW]
						<sup>a</sup> AMOXICLAV AMNEAL 500/125 [ED]	<sup>a</sup> Amoxyclav AN 500/125 [EA]
						<sup>a</sup> APO-Amoxicillin/ Clavulanic Acid 500/125 [TX]	<sup>a</sup> Curam Duo 500/125 [SZ]
						<sup>a</sup> Moxiclav Duo 500/125 [QA]	
			<sup>B</sup> 4.87	18.43	14.77	<sup>a</sup> Augmentin Duo [AS]	

**amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL**

1892N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	1	..	#15.54	17.11	<sup>a</sup> APO-Amoxicillin and Clavulanic Acid 125/31.25 [TX]	<sup>a</sup> Curam [SZ]
			<sup>B</sup> 3.45	#18.99	17.11	<sup>a</sup> Augmentin [AS]	

**■ AMOXYCILLIN + CLAVULANIC ACID**

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

Infections where resistance to amoxicillin is proven

**amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL**

5011R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#15.86	17.43	<sup>a</sup> APO-Amoxicillin and Clavulanic Acid 400/57 [TX]	<sup>a</sup> Curam Duo [SZ]
			<sup>B</sup> 4.84	#20.70	17.43	<sup>a</sup> Augmentin Duo 400 [AS]	

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

5006L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.86	15.07	<sup>a</sup> AlphaClav Duo Forte [AF]	<sup>a</sup> AMCLAVOX DUO FORTE 875/125 [RW]
						<sup>a</sup> AMOXICLAV AMNEAL 875/125 [ED]	<sup>a</sup> Amoxyclav AN 875/125 [EA]
						<sup>a</sup> AmoxyClav generichealth 875/125 [HQ]	<sup>a</sup> AmoxyClav GH 875/125 [GQ]
						<sup>a</sup> APO-Amoxicillin and Clavulanic Acid [TX]	<sup>a</sup> Chem mart Amoxicillin and Clavulanic Acid [CH]
						<sup>a</sup> Clavam 875 mg/125 mg [CR]	<sup>a</sup> Curam Duo Forte 875/125 [SZ]
						<sup>a</sup> Moxiclav Duo Forte 875/125 [QA]	<sup>a</sup> Terry White Chemists Amoxicillin and Clavulanic Acid [TW]
			<sup>B</sup> 6.24	20.10	15.07	<sup>a</sup> Augmentin Duo forte [AS]	

**amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10**

5008N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.56	14.77	<sup>a</sup> AlphaClav Duo [AF]	<sup>a</sup> AMCLAVOX DUO 500/125 [RW]
						<sup>a</sup> AMOXICLAV AMNEAL 500/125 [ED]	<sup>a</sup> Amoxyclav AN 500/125 [EA]
						<sup>a</sup> APO-Amoxicillin/ Clavulanic Acid 500/125 [TX]	<sup>a</sup> Curam Duo 500/125 [SZ]
						<sup>a</sup> Moxiclav Duo 500/125 [QA]	

# ANTIINFECTIVES FOR SYSTEMIC USE

			<sup>B</sup> 4.87	18.43	14.77	<sup>a</sup> Augmentin Duo [AS]	
<b>amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL</b>							
5009P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#15.54	17.11	<sup>a</sup> APO-Amoxicillin and Clavulanic Acid 125/31.25 [TX]	<sup>a</sup> Curam [SZ]
			<sup>B</sup> 3.45	#18.99	17.11	<sup>a</sup> Augmentin [AS]	

## ■ TICARCILLIN + CLAVULANIC ACID

### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

### **ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
10125X	10	..	..	*146.65	38.80	Timentin [AS]	
<b>DP</b>							

## ■ TICARCILLIN + CLAVULANIC ACID

### Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

### Restricted benefit

Septicaemia, suspected

### Restricted benefit

Septicaemia, proven

### **ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
10113G	10	..	..	*146.65	38.80	Timentin [AS]	
<b>NP</b>							

## OTHER BETA-LACTAM ANTIBACTERIALS

### *First-generation cephalosporins*

## ■ CEPHALEXIN

### **cephalexin 250 mg capsule, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3058Y	1	1	..	12.80	14.01	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Cefalexin Sandoz [SZ]
<b>NP MW</b>						<sup>a</sup> Cephalex 250 [CR]	<sup>a</sup> Cephalexin AN [EA]
						<sup>a</sup> Ialex [LN]	<sup>a</sup> Ibilex 250 [AF]
						<sup>a</sup> Rancef [RA]	
			<sup>B</sup> 3.76	16.56	14.01	<sup>a</sup> Keflex [AS]	

### **cephalexin 250 mg capsule, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3317N	1	..	..	12.80	14.01	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Cefalexin Sandoz [SZ]
<b>DP</b>						<sup>a</sup> Cephalex 250 [CR]	<sup>a</sup> Cephalexin AN [EA]
						<sup>a</sup> Ialex [LN]	<sup>a</sup> Ibilex 250 [AF]
						<sup>a</sup> Rancef [RA]	
			<sup>B</sup> 3.76	16.56	14.01	<sup>a</sup> Keflex [AS]	

### **cephalexin 500 mg capsule, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3119E	1	1	..	12.95	14.16	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Cefalexin Sandoz [SZ]
<b>NP MW</b>						<sup>a</sup> Cephalex 500 [CR]	<sup>a</sup> Cephalexin AN [EA]
						<sup>a</sup> Cephalexin generichealth [GQ]	<sup>a</sup> Ialex [LN]
						<sup>a</sup> Ibilex 500 [AF]	<sup>a</sup> Rancef [RA]
			<sup>B</sup> 5.47	18.42	14.16	<sup>a</sup> Keflex [AS]	

### **cephalexin 500 mg capsule, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3318P	1	..	..	12.95	14.16	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Cefalexin Sandoz [SZ]
<b>DP</b>						<sup>a</sup> Cephalex 500 [CR]	<sup>a</sup> Cephalexin AN [EA]
						<sup>a</sup> Cephalexin generichealth [GQ]	<sup>a</sup> Ialex [LN]
						<sup>a</sup> Ibilex 500 [AF]	<sup>a</sup> Rancef [RA]
			<sup>B</sup> 5.47	18.42	14.16	<sup>a</sup> Keflex [AS]	

**cephalexin 250 mg/5 mL powder for oral liquid, 100 mL**

3095X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#16.08	17.65	<sup>a</sup> Cefalexin Sandoz [SZ] <sup>a</sup> Ibilex 250 [AF]	<sup>a</sup> lalex [LN]
			<sup>B</sup> 5.69	#21.77	17.65	<sup>a</sup> Keflex [AS]	

**cephalexin 250 mg/5 mL powder for oral liquid, 100 mL**

3320R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#16.08	17.65	<sup>a</sup> Cefalexin Sandoz [SZ] <sup>a</sup> Ibilex 250 [AF]	<sup>a</sup> lalex [LN]
			<sup>B</sup> 5.69	#21.77	17.65	<sup>a</sup> Keflex [AS]	

**cephalexin 125 mg/5 mL powder for oral liquid, 100 mL**

3094W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#15.78	17.35	<sup>a</sup> Cefalexin Sandoz [SZ] <sup>a</sup> Ibilex 125 [AF]	<sup>a</sup> lalex [LN]
			<sup>B</sup> 4.15	#19.93	17.35	<sup>a</sup> Keflex [AS]	

**cephalexin 125 mg/5 mL powder for oral liquid, 100 mL**

3319Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#15.78	17.35	<sup>a</sup> Cefalexin Sandoz [SZ] <sup>a</sup> Ibilex 125 [AF]	<sup>a</sup> lalex [LN]
			<sup>B</sup> 4.15	#19.93	17.35	<sup>a</sup> Keflex [AS]	

▪ **CEPHALEXIN**

Authority required (STREAMLINED)

**6188**

Osteomyelitis

**cephalexin 500 mg capsule, 20**

10778G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*14.81	16.02	<sup>a</sup> APO-Cephalexin [TX] <sup>a</sup> Cephalex 500 [CR] <sup>a</sup> Cephalexin generichealth [GQ] <sup>a</sup> Ibilex 500 [AF]	<sup>a</sup> Cefalexin Sandoz [SZ] <sup>a</sup> Cephalexin AN [EA] <sup>a</sup> lalex [LN] <sup>a</sup> Rancef [RA]
			<sup>B</sup> 10.94	*25.75	16.02	<sup>a</sup> Keflex [AS]	

▪ **CEPHALEXIN**

Authority required (STREAMLINED)

**4243**

Prophylaxis of urinary tract infection

**cephalexin 250 mg capsule, 20**

2655R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*14.51	15.72	<sup>a</sup> APO-Cephalexin [TX] <sup>a</sup> Cephalex 250 [CR] <sup>a</sup> lalex [LN] <sup>a</sup> Rancef [RA]	<sup>a</sup> Cefalexin Sandoz [SZ] <sup>a</sup> Cephalexin AN [EA] <sup>a</sup> Ibilex 250 [AF]
			<sup>B</sup> 7.52	*22.03	15.72	<sup>a</sup> Keflex [AS]	

▪ **CEPHALOTHIN**

**cephalothin 1 g injection, 10 vials**

2964B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	25.56	26.77	Hospira Pty Limited [PF]

**cephalothin 1 g injection, 10 vials**

3376Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	25.56	26.77	Hospira Pty Limited [PF]

▪ **CEPHAZOLIN**

Restricted benefit

Cellulitis

**cephazolin 500 mg injection, 5 vials**

5477G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*17.39	18.60	Cefazolin-AFT [AE]

## ANTIINFECTIVES FOR SYSTEMIC USE

### cephazolin 2 g injection, 1 vial

5479J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	10	..	..	*38.85	38.80	Cephazolin Alphapharm [AF]

### ■ CEPHAZOLIN

**Note** For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

#### Restricted benefit

Cellulitis

### cephazolin 1 g injection, 5 vials

1799Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*20.87	22.08	<sup>a</sup> Cefazolin-AFT [AE]	<sup>a</sup> Hospira Cefazolin Sodium [PF]

### cephazolin 1 g injection, 10 vials

5478H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	20.87	22.08	<sup>a</sup> Cefazolin Sandoz [SZ]

### ■ CEPHAZOLIN

#### **Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

#### Restricted benefit

Septicaemia, suspected

#### Restricted benefit

Septicaemia, proven

### cephazolin 500 mg injection, 5 vials

1256D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*17.39	18.60	Cefazolin-AFT [AE]

### cephazolin 2 g injection, 1 vial

9326W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	10	..	..	*38.85	38.80	Cephazolin Alphapharm [AF]

### ■ CEPHAZOLIN

**Note** For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

#### **Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

#### Restricted benefit

Septicaemia, suspected

#### Restricted benefit

Septicaemia, proven

### cephazolin 1 g injection, 5 vials

1797N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*20.87	22.08	<sup>a</sup> Cefazolin-AFT [AE]	<sup>a</sup> Hospira Cefazolin Sodium [PF]

### cephazolin 1 g injection, 10 vials

1257E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	20.87	22.08	<sup>a</sup> Cefazolin Sandoz [SZ]

### *Second-generation cephalosporins*

### ■ CEFACLOR

**Caution** Serum sickness-like reactions have been reported with this drug, especially in children.

**cefactor 125 mg/5 mL powder for oral liquid, 100 mL**

2460L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	#17.16	18.73	<sup>a</sup> Aclor 125 [QA] <sup>a</sup> Keflor [AF]	<sup>a</sup> APO-Cefactor [TX]
			<sup>B</sup> 5.10	#22.26	18.73	<sup>a</sup> Ceclor [AS]	

**cefactor 125 mg/5 mL powder for oral liquid, 100 mL**

5046N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#17.16	18.73	<sup>a</sup> Aclor 125 [QA] <sup>a</sup> Keflor [AF]	<sup>a</sup> APO-Cefactor [TX]
			<sup>B</sup> 5.10	#22.26	18.73	<sup>a</sup> Ceclor [AS]	

**cefactor 250 mg/5 mL powder for oral liquid, 75 mL**

2461M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	#17.38	18.95	<sup>a</sup> Aclor 250 [QA] <sup>a</sup> Keflor [AF]	<sup>a</sup> APO-Cefactor [TX]
			<sup>B</sup> 5.31	#22.69	18.95	<sup>a</sup> Ceclor [AS]	

**cefactor 250 mg/5 mL powder for oral liquid, 75 mL**

5047P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#17.38	18.95	<sup>a</sup> Aclor 250 [QA] <sup>a</sup> Keflor [AF]	<sup>a</sup> APO-Cefactor [TX]
			<sup>B</sup> 5.31	#22.69	18.95	<sup>a</sup> Ceclor [AS]	

**cefactor 375 mg modified release tablet, 10**

1169M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	14.85	16.06	<sup>a</sup> APO-Cefactor CD [TX] <sup>a</sup> Karlor CD [LN] <sup>a</sup> Ozcef [RA]	<sup>a</sup> Cefactor GH [GQ] <sup>a</sup> Keflor CD [AF]
			<sup>B</sup> 6.26	21.11	16.06	<sup>a</sup> Ceclor CD [AS]	

**cefactor 375 mg modified release tablet, 10**

5045M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	14.85	16.06	<sup>a</sup> APO-Cefactor CD [TX] <sup>a</sup> Karlor CD [LN] <sup>a</sup> Ozcef [RA]	<sup>a</sup> Cefactor GH [GQ] <sup>a</sup> Keflor CD [AF]
			<sup>B</sup> 6.26	21.11	16.06	<sup>a</sup> Ceclor CD [AS]	

▪ **CEFUROXIME**

**cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL**

11191B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#26.11	27.68	Zinnat [AS]

**cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL**

11192C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	#26.11	27.68	Zinnat [AS]

**cefuroxime 250 mg tablet, 14**

5052X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	21.18	22.39	<sup>a</sup> Pharmacor Cefuroxime [CR]	<sup>a</sup> Zinnat [AS]

**cefuroxime 250 mg tablet, 14**

8292K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	21.18	22.39	<sup>a</sup> Pharmacor Cefuroxime [CR]	<sup>a</sup> Zinnat [AS]

**CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1**

2002J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#22.42	23.99	Zinnat [AS]

**CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1**

5499K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	#22.42	23.99	Zinnat [AS]

*Third-generation cephalosporins*

▪ **CEFOTAXIME**

Restricted benefit

## ANTIINFECTIVES FOR SYSTEMIC USE

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

### CEFOTAXIME Powder for injection 1 g, 10

1768C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	23.88	25.09	Hospira Pty Limited [PF]

### ▪ CEFOTAXIME

#### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

### CEFOTAXIME Powder for injection 2 g, 10

1769D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	34.74	35.95	Hospira Pty Limited [PF]

### ▪ CEFOTAXIME

#### **Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

#### Restricted benefit

Septicaemia, suspected

#### Restricted benefit

Septicaemia, proven

### CEFOTAXIME Powder for injection 1 g, 10

1758M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	23.88	25.09	Hospira Pty Limited [PF]

### CEFOTAXIME Powder for injection 2 g, 10

1759N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	34.74	35.95	Hospira Pty Limited [PF]

### ▪ CEFTRIAXONE

#### Restricted benefit

Gonorrhoea

### ceftriaxone 500 mg injection, 1 vial

9058R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	12.15	13.36	Ceftriaxone-AFT [AE]

### ▪ CEFTRIAXONE

#### **Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

#### Restricted benefit

Septicaemia, suspected

#### Restricted benefit

Septicaemia, proven

### ceftriaxone 500 mg injection, 1 vial

1783W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	..	..	*16.40	17.61	Ceftriaxone-AFT [AE]

### ▪ CEFTRIAXONE

**Note** Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 1 vial and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials are equivalent for the purposes of substitution.

#### **Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**ceftriaxone 2 g injection, 1 vial**

1785Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	..	..	*22.25	23.46	<sup>a</sup> Ceftriaxone-AFT [AE]

**ceftriaxone 2 g injection, 5 vials**

11169W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	22.22	23.43	<sup>a</sup> Ceftriaxone Alphapharm [AF]

**■ CEFTRIAZONE**

**Note** For item codes 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**CEFTRIAZONE Powder for injection 1 g, 5**

1788D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	22.11	23.32	<sup>a</sup> Ceftriaxone Alphapharm [AF]

**ceftriaxone 1 g injection, 1 vial**

1784X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	5	..	..	*22.10	23.31	<sup>a</sup> Ceftriaxone-AFT [AE]	<sup>a</sup> Ceftriaxone Sandoz [SZ]
						<sup>a</sup> Hospira Ceftriaxone [PF]	

**Fourth-generation cephalosporins**
**■ CEFEPIME**
**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Febrile neutropenia

**CEFEPIME Powder for injection 1 g (as hydrochloride), 1**

8315P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	10	..	..	*79.35	38.80	<sup>a</sup> Cefepime-AFT [AE]	<sup>a</sup> Cefepime Alphapharm [AF]
						<sup>a</sup> Cefepime Kabi [PK]	<sup>a</sup> DBL Cefepime [PF]
						<sup>a</sup> Omegapharm Pty Ltd [OE]	

**CEFEPIME Powder for injection 2 g (as hydrochloride), 1**

8316Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	10	..	..	*129.55	38.80	<sup>a</sup> Cefepime-AFT [AE]	<sup>a</sup> Cefepime Alphapharm [AF]
						<sup>a</sup> Cefepime Kabi [PK]	<sup>a</sup> DBL Cefepime [PF]
						<sup>a</sup> Omegapharm Pty Ltd [OE]	

**SULFONAMIDES AND TRIMETHOPRIM**
**Trimethoprim and derivatives**
**■ TRIMETHOPRIM**
**trimethoprim 300 mg tablet, 7**

2922T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.79	14.00	<sup>a</sup> Alprim [AF]
			<sup>B</sup> 3.68	16.47	14.00	<sup>a</sup> Triprim [RW]

▪ **TRIMETHOPRIM**

**Authority required (STREAMLINED)**

**4243**

Prophylaxis of urinary tract infection

**trimethoprim 300 mg tablet, 7**

2666H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*14.49	15.70	<sup>a</sup> Alprim [AF]
			<sup>B</sup> 7.36	*21.85	15.70	<sup>a</sup> Triprim [RW]

▪ **TRIMETHOPRIM**

**Restricted benefit**

Prostatitis

**trimethoprim 300 mg tablet, 7**

10785P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*17.91	19.12	<sup>a</sup> Alprim [AF]
			<sup>B</sup> 14.72	*32.63	19.12	<sup>a</sup> Triprim [RW]

**Combinations of sulfonamides and trimethoprim, incl. derivatives**

▪ **TRIMETHOPRIM + SULFAMETHOXAZOLE**

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

2951H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.98	14.19	<sup>a</sup> Resprim Forte [AF]
			<sup>B</sup> 2.17	15.15	14.19	<sup>a</sup> Bactrim DS [RO]
			<sup>B</sup> 4.17	17.15	14.19	<sup>a</sup> Septrin Forte [RW]

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

3390K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	12.98	14.19	<sup>a</sup> Resprim Forte [AF]
			<sup>B</sup> 2.17	15.15	14.19	<sup>a</sup> Bactrim DS [RO]
			<sup>B</sup> 4.17	17.15	14.19	<sup>a</sup> Septrin Forte [RW]

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

3103H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	13.27	14.48	Bactrim [RO]
			<sup>B</sup> 5.69	18.96	14.48	Septrin [RW]

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

3391L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	13.27	14.48	Bactrim [RO]
			<sup>B</sup> 5.69	18.96	14.48	Septrin [RW]

▪ **TRIMETHOPRIM + SULFAMETHOXAZOLE**

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**Authority required (STREAMLINED)**

**6201**

Prophylaxis of Pneumocystis jiroveci pneumonia

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

10784N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	2	..	*16.75	17.96	<sup>a</sup> Resprim Forte [AF]
			<sup>B</sup> 6.51	*23.26	17.96	<sup>a</sup> Bactrim DS [RO]
			<sup>B</sup> 12.51	*29.26	17.96	<sup>a</sup> Septrin Forte [RW]

**MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS**

*Macrolides*

▪ **AZITHROMYCIN**

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

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

**Restricted benefit**

Trachoma

**azithromycin 200 mg/5 mL powder for oral liquid, 15 mL**

8201P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	#26.26	27.83	Zithromax [PF]

**azithromycin 500 mg tablet, 2**

8336R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.37	16.58	<sup>a</sup> APO-Azithromycin [TX] <sup>a</sup> Azithromycin Sandoz [SZ] <sup>a</sup> Terry White Chemists Azithromycin [TW]	<sup>a</sup> Azithromycin Mylan [AF] <sup>a</sup> Chem mart Azithromycin [CH] <sup>a</sup> Zithromax [PF]

▪ **AZITHROMYCIN**

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

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

**Restricted benefit**

Urethritis

**Clinical criteria:**

- The condition must be uncomplicated and due to Chlamydia trachomatis.

**Restricted benefit**

Cervicitis

**Clinical criteria:**

- The condition must be uncomplicated and due to Chlamydia trachomatis.

**azithromycin 500 mg tablet, 2**

8200N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.37	16.58	<sup>a</sup> APO-Azithromycin [TX] <sup>a</sup> Azithromycin Sandoz [SZ] <sup>a</sup> Terry White Chemists Azithromycin [TW]	<sup>a</sup> Azithromycin Mylan [AF] <sup>a</sup> Chem mart Azithromycin [CH] <sup>a</sup> Zithromax [PF]

▪ **CLARITHROMYCIN**

**clarithromycin 250 mg tablet, 14**

8318T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	14.05	15.26	<sup>a</sup> APO-Clarithromycin [TX] <sup>a</sup> Clarac [ED] <sup>a</sup> Clarithro 250 [RW] <sup>a</sup> Clarithromycin Sandoz [SZ] <sup>a</sup> Terry White Chemists Clarithromycin [TW]	<sup>a</sup> Chem mart Clarithromycin [CH] <sup>a</sup> Clarihexal [HX] <sup>a</sup> Clarithromycin AN [EA] <sup>a</sup> Kalixocin [AF]
			<sup>b</sup> 3.49	17.54	15.26	<sup>a</sup> Klacid [GO]	

▪ **CLARITHROMYCIN**

**Restricted benefit**

Bordetella pertussis

**Restricted benefit**

Atypical mycobacterial infections

**clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL**

9192T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	#29.93	31.50	Klacid [GO]

▪ **ERYTHROMYCIN**

**erythromycin 250 mg enteric capsule, 25**

1404X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	15.87	17.08	<sup>a</sup> Mayne Pharma Erythromycin [YT] <sup>a</sup> Eryc [YN]
			<sup>b</sup> 2.53	18.40	17.08	

**erythromycin 250 mg enteric capsule, 25**

3325B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	15.87	17.08	<sup>a</sup> Mayne Pharma Erythromycin [YT] <sup>a</sup> Eryc [YN]
			<sup>b</sup> 2.53	18.40	17.08	

▪ **ERYTHROMYCIN**

**Authority required (STREAMLINED)**

**6160**

Severe acne

**Clinical criteria:**

- The condition must be one in which tetracycline therapy is inappropriate.

**erythromycin 250 mg enteric capsule, 25**

10780J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*20.65	21.86	<sup>a</sup> Mayne Pharma Erythromycin [YT]
			<sup>b</sup> 5.06	*25.71	21.86	<sup>a</sup> Eryc [YN]

▪ **ERYTHROMYCIN ETHYLSUCCINATE**

**erythromycin (as ethylsuccinate) 400 mg tablet, 25**

2750R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	15.99	17.20	E-Mycin [AF]

**erythromycin (as ethylsuccinate) 400 mg tablet, 25**

3336N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	15.99	17.20	E-Mycin [AF]

**erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL**

2424N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#18.62	20.19	<sup>a</sup> E-Mycin 200 [AF]
			<sup>b</sup> 2.36	#20.98	20.19	<sup>a</sup> E.E.S. 200 [GH]

**erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL**

3334L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#18.62	20.19	<sup>a</sup> E-Mycin 200 [AF]
			<sup>b</sup> 2.36	#20.98	20.19	<sup>a</sup> E.E.S. 200 [GH]

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

2428T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	#19.93	21.50	<sup>a</sup> E-Mycin 400 [AF]
			<sup>b</sup> 2.38	#22.31	21.50	<sup>a</sup> E.E.S. Granules [GH]

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

3337P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#19.93	21.50	<sup>a</sup> E-Mycin 400 [AF]
			<sup>b</sup> 2.38	#22.31	21.50	<sup>a</sup> E.E.S. Granules [GH]

▪ **ERYTHROMYCIN ETHYLSUCCINATE**

Authority required (STREAMLINED)

**6160**

Severe acne

**Clinical criteria:**

- The condition must be one in which tetracycline therapy is inappropriate.

**erythromycin (as ethylsuccinate) 400 mg tablet, 25**

10789W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*20.89	22.10	E-Mycin [AF]

▪ **ROXITHROMYCIN**

**roxithromycin 50 mg dispersible tablet, 10**

5259T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.72	17.93	Rulide D [SW]

**roxithromycin 50 mg dispersible tablet, 10**

8129W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	16.72	17.93	Rulide D [SW]

**roxithromycin 300 mg tablet, 5**

5261X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	13.57	14.78	<sup>a</sup> APO-Roxithromycin [TX]	<sup>a</sup> Biaxisig [AV]
						<sup>a</sup> Chem mart Roxithromycin [CH]	<sup>a</sup> Roxar 300 [RW]
						<sup>a</sup> Roximycin [AF]	<sup>a</sup> Roxithromycin AN [EA]

<sup>a</sup> Roxithromycin-GA [ED]      <sup>a</sup> Roxithromycin GH [GQ]  
<sup>a</sup> Roxithromycin Sandoz [SZ]      <sup>a</sup> Terry White Chemists  
 Roxithromycin [TW]

<sup>B</sup>1.62      15.19      14.78      <sup>a</sup> Rulide [SW]

**roxithromycin 300 mg tablet, 5**

8016X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	13.57	14.78	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Chem mart Roxithromycin [CH] <sup>a</sup> Roximycin [AF] <sup>a</sup> Roxithromycin-GA [ED] <sup>a</sup> Roxithromycin Sandoz [SZ]	<sup>a</sup> Biaxsig [AV] <sup>a</sup> Roxar 300 [RW] <sup>a</sup> Roxithromycin AN [EA] <sup>a</sup> Roxithromycin GH [GQ] <sup>a</sup> Terry White Chemists Roxithromycin [TW]
			<sup>B</sup> 1.62	15.19	14.78	<sup>a</sup> Rulide [SW]	

**roxithromycin 150 mg tablet, 10**

1760P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	13.57	14.78	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Chem mart Roxithromycin [CH] <sup>a</sup> Roximycin [AF] <sup>a</sup> Roxithromycin-GA [ED] <sup>a</sup> Roxithromycin Sandoz [SZ]	<sup>a</sup> Biaxsig [AV] <sup>a</sup> Roxar 150 [RW] <sup>a</sup> Roxithromycin AN [EA] <sup>a</sup> Roxithromycin GH [GQ] <sup>a</sup> Terry White Chemists Roxithromycin [TW]
			<sup>B</sup> 1.62	15.19	14.78	<sup>a</sup> Rulide [SW]	

**roxithromycin 150 mg tablet, 10**

5260W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	13.57	14.78	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Chem mart Roxithromycin [CH] <sup>a</sup> Roximycin [AF] <sup>a</sup> Roxithromycin-GA [ED] <sup>a</sup> Roxithromycin Sandoz [SZ]	<sup>a</sup> Biaxsig [AV] <sup>a</sup> Roxar 150 [RW] <sup>a</sup> Roxithromycin AN [EA] <sup>a</sup> Roxithromycin GH [GQ] <sup>a</sup> Terry White Chemists Roxithromycin [TW]
			<sup>B</sup> 1.62	15.19	14.78	<sup>a</sup> Rulide [SW]	

**Lincosamides**

▪ **CLINDAMYCIN**

**Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

5057E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	17.96	19.17	<sup>a</sup> APO-Clindamycin [TX] <sup>a</sup> Chem mart Clindamycin [CH] <sup>a</sup> Clindamycin BNM [BZ] <sup>a</sup> Clindamyk [AF]	<sup>a</sup> Calindamin [RW] <sup>a</sup> Cleocin [FZ] <sup>a</sup> Clindamycin-Link [LI] <sup>a</sup> Terry White Chemists Clindamycin [TW]
			<sup>B</sup> 8.60	26.56	19.17	<sup>a</sup> Dalacin C [PF]	

▪ **CLINDAMYCIN**

**Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

3138E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	2	1	..	*24.83	26.04	<sup>a</sup> APO-Clindamycin [TX] <sup>a</sup> Chem mart Clindamycin [CH] <sup>a</sup> Clindamycin BNM [BZ] <sup>a</sup> Clindamyk [AF]	<sup>a</sup> Calindamin [RW] <sup>a</sup> Cleocin [FZ] <sup>a</sup> Clindamycin-Link [LI] <sup>a</sup> Terry White Chemists Clindamycin [TW]
			<sup>B</sup> 17.20	*42.03	26.04	<sup>a</sup> Dalacin C [PF]	

## ANTIINFECTIVES FOR SYSTEMIC USE

### ■ LINCOMYCIN

#### lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

2530E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	142.86	38.80	Lincocin [PF]

#### lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

5144R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	142.86	38.80	Lincocin [PF]

## AMINOGLYCOSIDE ANTIBACTERIALS

### Other aminoglycosides

### ■ GENTAMICIN

#### gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules

2824P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	22.61	23.82	Pfizer Australia Pty Ltd [PF]

### ■ TOBRAMYCIN

#### **Restricted benefit**

Pseudomonas aeruginosa infection

#### Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- The treatment must be systemic.

#### tobramycin 500 mg/5 mL injection, 10 x 5 mL vials

9480Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	279.78	38.80	Tobra-Day [PL]

### ■ TOBRAMYCIN

#### **Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

#### **Restricted benefit**

Septicaemia, suspected

#### **Restricted benefit**

Septicaemia, proven

#### tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

1356J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*48.31	38.80	<sup>a</sup> Hospira Pty Limited [PF]	<sup>a</sup> Tobramycin Mylan [AF]

#### tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5

8872Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*48.31	38.80	Pfizer Australia Pty Ltd [PF]

### ■ TOBRAMYCIN

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required (STREAMLINED)**

#### **4456**

Proven Pseudomonas aeruginosa infection

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, **AND**
- Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

#### Population criteria:

- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

10066T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2432.37	38.80	TOBI podhaler [NV]

**■ TOBRAMYCIN**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**4513**

Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

**Population criteria:**

- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

10074F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2432.37	38.80	TOBI podhaler [NV]

**■ TOBRAMYCIN**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**5520**

Proven Pseudomonas aeruginosa infection

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

**tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules**

5442K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1048.47	38.80	<sup>a</sup> Tobi [NV]	<sup>a</sup> Tobramycin AN [EA]

**QUINOLONE ANTIBACTERIALS**
*Fluoroquinolones*
**■ CIPROFLOXACIN**
**Authority required**

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

**Authority required**

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority required**

Infection

**Clinical criteria:**

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Perichondritis of the pinna

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**ciprofloxacin 500 mg tablet, 14**

1209P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.35	18.56	<sup>a</sup> APO-Ciprofloxacin [TX]	<sup>a</sup> C-Flox 500 [AL]
						<sup>a</sup> Cifran [RA]	<sup>a</sup> Ciprofloxacin AN [EA]
						<sup>a</sup> Ciprofloxacin-BW [GQ]	<sup>a</sup> Ciprofloxacin Sandoz [SZ]
						<sup>a</sup> Ciprol 500 [RW]	<sup>a</sup> Loxip 500 [DO]
						<sup>b</sup> 2.43	19.78

**ciprofloxacin 750 mg tablet, 14**

1210Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	20.52	21.73	<sup>a</sup> APO-Ciprofloxacin [TX]	<sup>a</sup> C-Flox 750 [AL]
						<sup>a</sup> Cifran [RA]	<sup>a</sup> Ciprofloxacin AN [EA]
						<sup>a</sup> Ciprofloxacin Sandoz [SZ]	<sup>a</sup> Ciprol 750 [RW]
						<sup>a</sup> Loxip 750 [DO]	

▪ **CIPROFLOXACIN**

**Authority required**

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

**Authority required**

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority required**

Infection

**Clinical criteria:**

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Perichondritis of the pinna

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Gonorrhoea

**ciprofloxacin 250 mg tablet, 14**

1208N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.29	15.50	<sup>a</sup> APO-Ciprofloxacin [TX]	<sup>a</sup> C-Flox 250 [AL]
						<sup>a</sup> Ciprofloxacin Sandoz [SZ]	<sup>a</sup> Ciprol 250 [RW]
				<sup>B</sup> 1.74	16.03	15.50	<sup>a</sup> Ciproxin 250 [BN]

▪ **NORFLOXACIN**

**Authority required**

Acute bacterial enterocolitis

**Authority required**

Complicated urinary tract infection

**norfloxacin 400 mg tablet, 14**

3010K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	14.67	15.88	<sup>a</sup> GenRx Norfloxacin [GX]	<sup>a</sup> Nufloxib [AF]
						<sup>a</sup> Roxin [RW]	

**OTHER ANTIBACTERIALS**

*Glycopeptide antibacterials*

▪ **VANCOMYCIN**

**Restricted benefit**

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 500 mg injection, 1 vial**

3130R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*21.17	22.38	<sup>a</sup> Hospira Pty Limited [PF]	<sup>a</sup> Vancomycin Alphapharm [AF]

**vancomycin 1 g injection, 1 vial**

2269K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	17.47	18.68	<sup>a</sup> Hospira Pty Limited [PF]	<sup>a</sup> Vancomycin Alphapharm [AF]
						<sup>a</sup> Vycin IV [EA]	

▪ **VANCOMYCIN**

**Restricted benefit**

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 500 mg injection, 1 vial**

3323X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	2	..	..	*21.17	22.38	<sup>a</sup> Hospira Pty Limited [PF]	<sup>a</sup> Vancomycin Alphapharm [AF]

**vancomycin 1 g injection, 1 vial**

5083M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.47	18.68	<sup>a</sup> Hospira Pty Limited [PF]	<sup>a</sup> Vancomycin Alphapharm [AF]
						<sup>a</sup> Vycin IV [EA]	

▪ **VANCOMYCIN**

**Restricted benefit**

# ANTIINFECTIVES FOR SYSTEMIC USE

Endophthalmitis  
**Restricted benefit**  
 Infection  
**Clinical criteria:**

- The treatment must be initiated in a hospital, **AND**
- The condition must be one in which vancomycin is an appropriate antibiotic.

## vancomycin 500 mg injection, 1 vial

3131T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	..	..	*36.30	37.51	<sup>a</sup> Hospira Pty Limited [PF]	<sup>a</sup> Vancomycin Alphapharm [AF]

## vancomycin 1 g injection, 1 vial

2270L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*30.22	31.43	<sup>a</sup> Hospira Pty Limited [PF] <sup>a</sup> Vycin IV [EA]	<sup>a</sup> Vancomycin Alphapharm [AF]

## Steroid antibacterials

### ■ FUSIDATE

**Restricted benefit**  
 Serious staphylococcal infections  
**Clinical criteria:**

- The treatment must be used in combination with another antibiotic, **AND**
- The condition must be proven to be due to a staphylococcus.

## sodium fusidate 250 mg tablet, 36

2312Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	84.04	38.80	Fucidin [CS]

### ■ FUSIDATE

**Authority required (STREAMLINED)**

**6133**  
 Osteomyelitis  
**Clinical criteria:**

- The condition must be methicillin-resistant staphylococcal aureus (MRSA), **AND**
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

## sodium fusidate 250 mg tablet, 36

10782L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*156.99	38.80	Fucidin [CS]

## Imidazole derivatives

### ■ METRONIDAZOLE

## metronidazole 500 mg suppository, 10

1642K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	25.65	26.86	Flagyl [SW]

## metronidazole 500 mg suppository, 10

5157K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	25.65	26.86	Flagyl [SW]

## metronidazole 200 mg/5 mL oral liquid, 100 mL

1630T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	21.87	23.08	Flagyl S [SW]

## metronidazole 200 mg/5 mL oral liquid, 100 mL

3341W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	21.87	23.08	Flagyl S [SW]

## metronidazole 200 mg tablet, 21

1636D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.36	13.57	<sup>a</sup> Metrogyl 200 [AF]	<sup>a</sup> Metronide 200 [AV]
			<sup>b</sup> 2.00	14.36	13.57	<sup>a</sup> Flagyl [SW]	

**metronidazole 200 mg tablet, 21**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3339R	1	..	..	12.36	13.57	<sup>a</sup> Metrogyl 200 [AF]	<sup>a</sup> Metronide 200 [AV]
DP			<sup>B</sup> 2.00	14.36	13.57	<sup>a</sup> Flagyl [SW]	

▪ **METRONIDAZOLE**

**Restricted benefit**

Anaerobic infections

**metronidazole 400 mg tablet, 21**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1621H	1	1	..	14.07	15.28	<sup>a</sup> Metrogyl 400 [AF]	<sup>a</sup> Metronide 400 [AV]
NP			<sup>B</sup> 2.00	16.07	15.28	<sup>a</sup> Flagyl [SW]	

▪ **METRONIDAZOLE**

**Restricted benefit**

Acute anaerobic sepsis

**Treatment criteria:**

- Must be treated in a hospital.

**metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1832K	1	..	..	20.81	22.02	Metronidazole Sandoz IV [SZ]
DP						

▪ **METRONIDAZOLE**

**Restricted benefit**

Anaerobic infections

**metronidazole 400 mg tablet, 21**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5155H	1	..	..	14.07	15.28	<sup>a</sup> Metrogyl 400 [AF]	<sup>a</sup> Metronide 400 [AV]
DP			<sup>B</sup> 2.00	16.07	15.28	<sup>a</sup> Flagyl [SW]	

▪ **METRONIDAZOLE**

**Restricted benefit**

Prophylaxis to prevent infection

**Clinical criteria:**

- Patient must be undergoing large bowel surgery.

**Restricted benefit**

Acute anaerobic sepsis

**Treatment criteria:**

- Must be treated in a hospital.

**metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1821W	1	..	..	20.81	22.02	Metronidazole Sandoz IV [SZ]
NP						

▪ **TINIDAZOLE**

**tinidazole 500 mg tablet, 4**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1465D	1	..	..	14.89	16.10	<sup>a</sup> Simplotan [FZ]
NP			<sup>B</sup> 6.70	21.59	16.10	<sup>a</sup> Fasigyn [PF]

*Nitrofurans derivatives*

▪ **NITROFURANTOIN**

Caution Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

**nitrofurantoin 100 mg capsule, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1693D	1	1	..	32.12	33.33	Macrochantin [PF]
NP MW						

**nitrofurantoin 50 mg capsule, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1692C	1	1	..	26.08	27.29	Macrochantin [PF]
NP MW						

*Other antibacterials*

▪ **HEXAMINE HIPPURATE**

hexamine hippurate 1 g tablet, 100

3124K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	44.11	38.80	Hiprex [IA]

▪ **ANTIMYCOTICS FOR SYSTEMIC USE**

**ANTIMYCOTICS FOR SYSTEMIC USE**

*Triazole derivatives*

▪ **FLUCONAZOLE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Cryptococcal meningitis

**Restricted benefit**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Restricted benefit**

Candida infections

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 200 mg capsule, 28**

1475P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	51.46	38.80	<sup>a</sup> APO-Fluconazole [TX] <sup>a</sup> Dizole 200 [AF] <sup>a</sup> Fluzole 200 [RW]	<sup>a</sup> Diflucan [PF] <sup>a</sup> Fluconazole Sandoz [SZ] <sup>a</sup> Ozole [RA]

**fluconazole 100 mg capsule, 28**

1472L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	31.81	33.02	<sup>a</sup> Diflucan [PF] <sup>a</sup> Fluconazole Sandoz [SZ]	<sup>a</sup> Dizole 100 [AF] <sup>a</sup> Ozole [RA]

**fluconazole 100 mg/50 mL injection, 50 mL vial**

1473M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	7	..	..	*21.08	22.29	Fluconazole Sandoz [SZ]

**fluconazole 50 mg capsule, 28**

1471K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.73	22.94	<sup>a</sup> Dizole 50 [AF] <sup>a</sup> Ozole [RA]	<sup>a</sup> Fluconazole Sandoz [SZ]
			<sup>b</sup> 6.00	27.73	22.94	<sup>a</sup> Diflucan [PF]	

**fluconazole 400 mg/200 mL injection, 200 mL bag**

1757L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	15.33	16.54	Fluconazole Alphapharm [AF]

▪ **FLUCONAZOLE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Cryptococcal meningitis

**Clinical criteria:**

- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Candida infections

**Clinical criteria:**

- The condition must be serious or life-threatening, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**fluconazole 50 mg/5 mL powder for oral liquid, 35 mL**

5446P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	#67.36	38.80	Diflucan [PF]

▪ **FLUCONAZOLE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the forms fluconazole 200 mg/100 mL injection, 100 mL vial and fluconazole 200 mg/100 mL injection, 100 mL bag are equivalent for the purposes of substitution.

**Restricted benefit**

Cryptococcal meningitis

**Restricted benefit**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Restricted benefit**

Candida infections

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 200 mg/100 mL injection, 100 mL bag**

11139G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	7	..	..	*46.35	38.80	<sup>a</sup> Fluconazole Alphapharm [AF]

**fluconazole 200 mg/100 mL injection, 100 mL vial**

1474N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	7	..	..	*46.35	38.80	<sup>a</sup> Fluconazole Sandoz [SZ]

▪ **ITRACONAZOLE**

**Note** One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole (Sporanox). The recommended dose of Lozanoc is therefore half the recommended dose for Sporanox. Lozanoc 50 mg capsules and Sporanox 100 mg capsules are not interchangeable.

**Note** Not for use in superficial mycoses

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Systemic aspergillosis

**Restricted benefit**

Systemic sporotrichosis

**Restricted benefit**

Systemic histoplasmosis

**Restricted benefit**

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Restricted benefit**

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**itraconazole 100 mg capsule, 60**

8196J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	128.66	38.80	<sup>a</sup> APO-Itraconazole [TX] <sup>a</sup> ITRANOX [RW]	<sup>a</sup> Itracap [AF] <sup>a</sup> Sporanox [JC]

**itraconazole 50 mg capsule, 60**

10732W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	128.66	38.80	Lozanoc [YN]

▪ **POSACONAZOLE**

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Invasive aspergillosis

**Clinical criteria:**

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

No more than 6 months therapy per episode will be PBS-subsidised

**Authority required**

Fungal infection

**Clinical criteria:**

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**posaconazole 100 mg modified release tablet, 24**

10460M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	834.65	38.80	Noxafil [MK]

**■ POSACONAZOLE**

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Invasive aspergillosis

**Clinical criteria:**

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Authority required**

Fungal infection

**Clinical criteria:**

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

No more than 6 months therapy per episode will be PBS-subsidised

**posaconazole 40 mg/mL oral liquid, 105 mL**

9360P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	691.97	38.80	Noxafil [MK]

▪ **VORICONAZOLE**

**Note** For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note** For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR
- Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

10168E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#496.21	38.80	Vfend [PF]

**voriconazole 200 mg tablet, 56**

10198R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	1590.34	38.80	<sup>a</sup> Vfend [PF] <sup>a</sup> Voriconazole Sandoz [SZ] <sup>a</sup> Vzole [RW]	<sup>a</sup> Voriconazole APOTEX [TX] <sup>a</sup> Vttack [AF]

**voriconazole 50 mg tablet, 56**

10173K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	411.53	38.80	<sup>a</sup> Vfend [PF] <sup>a</sup> Voriconazole Sandoz [SZ] <sup>a</sup> Vzole [RW]	<sup>a</sup> Voriconazole APOTEX [TX] <sup>a</sup> Vttack [AF]

▪ **VORICONAZOLE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be immunocompromised.

**Authority required**

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by *Scedosporium* species; OR
- The condition must be caused by *Fusarium* species.

**Authority required**

Serious *Candida* infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

**Authority required**

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**voriconazole 200 mg tablet, 56**

9364W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	1590.34	38.80	<sup>a</sup> Vfend [PF] <sup>a</sup> Voriconazole Sandoz [SZ] <sup>a</sup> Vzole [RW]	<sup>a</sup> Voriconazole APOTEX [TX] <sup>a</sup> Vttack [AF]

**voriconazole 50 mg tablet, 56**

9363T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	411.53	38.80	<sup>a</sup> Vfend [PF] <sup>a</sup> Voriconazole Sandoz [SZ] <sup>a</sup> Vzole [RW]	<sup>a</sup> Voriconazole APOTEX [TX] <sup>a</sup> Vttack [AF]

**■ VORICONAZOLE**

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be immunocompromised.

**Authority required**

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by *Scedosporium* species; OR
- The condition must be caused by *Fusarium* species.

**Authority required**

Serious *Candida* infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

**Authority required**

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

9452L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#496.21	38.80	Vfend [PF]

**■ ANTIMYCOBACTERIALS**
**DRUGS FOR TREATMENT OF TUBERCULOSIS**

*Hydrazides*

**■ ISONIAZID**
**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**isoniazid 100 mg tablet, 100**

1554T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	23.53	24.74	Arrow Pharma Pty Ltd [RW]

**DRUGS FOR TREATMENT OF LEPRA**

*Drugs for treatment of lepra*

## ANTIINFECTIVES FOR SYSTEMIC USE

### ■ DAPSONE

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### dapsone 25 mg tablet, 100

8801F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	288.57	38.80	Link Medical Products Pty Ltd [LM]

#### dapsone 100 mg tablet, 100

1272Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	353.02	38.80	Link Medical Products Pty Ltd [LM]

### ■ RIFAMPICIN

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Leprosy

**Population criteria:**

- Patient must be an adult.

#### rifampicin 150 mg capsule, 100

1982H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	281.44	38.80	Rimycin 150 [AF]

#### rifampicin 300 mg capsule, 100

1983J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	133.02	38.80	Rimycin 300 [AF]

### ■ RIFAMPICIN

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Meningococcal disease

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be a carrier of the disease; OR
- Patient must be in close contact with people who have the disease.

**Restricted benefit**

Haemophilus influenzae type B

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be in contact with people who have the disease.

#### rifampicin 150 mg capsule, 10

1981G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	37.82	38.80	Rimycin 150 [AF]

#### rifampicin 100 mg/5 mL oral liquid, 60 mL

8025J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	30.85	32.06	Rifadin [SW]

#### rifampicin 300 mg capsule, 10

1984K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	23.28	24.49	Rimycin 300 [AF]

## ■ ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

▪ **ACICLOVIR**

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

**5942**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**aciclovir 200 mg tablet, 90**

1007B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.63	36.84	<sup>a</sup> Aciclovir 200 [CR]	<sup>a</sup> Aciclovir AN [ED]
						<sup>a</sup> Aciclovir GH [GQ]	<sup>a</sup> Aciclovir Sandoz [HX]
						<sup>a</sup> Acyclo-V 200 [AF]	<sup>a</sup> GenRx Aciclovir [GX]
						<sup>a</sup> Lovir [EA]	<sup>a</sup> Ozvir [RA]
						<sup>b</sup> 0.91	36.54

▪ **ACICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

**5967**

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)**

**5959**

Herpes zoster ophthalmicus

**aciclovir 800 mg tablet, 35**

1052J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	40.79	38.80	<sup>a</sup> Aciclovir 800 [CR]	<sup>a</sup> Aciclovir Sandoz [HX]
						<sup>a</sup> GenRx Aciclovir [GX]	

▪ **ACICLOVIR**

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

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

**Note** For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**5936**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**aciclovir 200 mg tablet, 25**

1003T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*24.73	25.94	<sup>a</sup> Aciclovir Sandoz [HX]

**aciclovir 200 mg tablet, 50**

1555W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.72	25.93	<sup>a</sup> GenRx Aciclovir [GX]

▪ **FAMCICLOVIR**

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

**5971**

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 250 mg tablet, 56**

8217L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	71.94	38.80	<sup>a</sup> APO-Famciclovir [TX]	<sup>a</sup> Auro-Famciclovir 250 [DO]

- <sup>a</sup> Ezovir [AF]
- <sup>a</sup> Famciclovir FBM [FO]
- <sup>a</sup> Famciclovir generichealth 250 [GQ]
- <sup>a</sup> Famciclovir SCP 250 [CR]
- <sup>a</sup> Famvir [HX]
- <sup>a</sup> Famciclovir AN [EA]
- <sup>a</sup> Famciclovir-GA [ED]
- <sup>a</sup> Famciclovir Sandoz [SZ]
- <sup>a</sup> Famlo [RA]
- <sup>a</sup> Favic 250 [RW]

▪ **FAMCICLOVIR**

**Note** Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

**5937**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 250 mg tablet, 20**

2274Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	32.82	34.03	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famciclovir Sandoz [SZ] <sup>a</sup> Favic 250 [RW]	<sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED] <sup>a</sup> Famvir [HX]

**famciclovir 125 mg tablet, 40**

8092X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	32.82	34.03	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED] <sup>a</sup> Favic 125 [RW]	<sup>a</sup> Auro-Famciclovir 125 [DO] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famvir [HX]

▪ **FAMCICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

**5951**

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 250 mg tablet, 21**

8002E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	33.91	35.12	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED]  <sup>a</sup> Famciclovir Sandoz [SZ] <sup>a</sup> Famlo [RA] <sup>a</sup> Favic 250 [RW]	<sup>a</sup> Auro-Famciclovir 250 [DO] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famciclovir generichealth 250 [GQ] <sup>a</sup> Famciclovir SCP 250 [CR] <sup>a</sup> Famvir [HX]

▪ **FAMCICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

**5943**

Herpes zoster

**Clinical criteria:**

- Patient must be immunocompromised, **AND**
- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 500 mg tablet, 30**

8897G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	43.69	38.80	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Famciclovir AN [EA]	<sup>a</sup> Auro-Famciclovir 500 [DO] <sup>a</sup> Famciclovir Sandoz [SZ]

<sup>a</sup> Famvir [HX]

<sup>a</sup> Favic 500 [RW]

▪ **FAMCICLOVIR**

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Authority required (STREAMLINED)**

**5954**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

**Clinical criteria:**

- Patient must be immunocompromised.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

**5947**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

**5948**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

**5949**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must present with other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 500 mg tablet, 56**

8896F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	71.95	38.80	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED]  <sup>a</sup> Famciclovir Sandoz [SZ] <sup>a</sup> Favic 500 [RW]	<sup>a</sup> Auro-Famciclovir 500 [DO] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famciclovir generichealth 500 [GQ] <sup>a</sup> Famvir [HX]

▪ **RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

# ANTIINFECTIVES FOR SYSTEMIC USE

General

## ribavirin 400 mg tablet, 28

10647J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	161.62	38.80	Ibavyr [IX]

## ribavirin 200 mg tablet, 28

10937P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	86.35	38.80	Ibavyr [IX]

## ribavirin 600 mg tablet, 28

10665H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	238.48	38.80	Ibavyr [IX]

### ■ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

#### Authority required

Chronic hepatitis C infection

#### **Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

#### **Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

## ribavirin 400 mg tablet, 28

10673R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	161.62	38.80	Ibavyr [IX]

## ribavirin 200 mg tablet, 28

10928E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	86.35	38.80	Ibavyr [IX]

## ribavirin 600 mg tablet, 28

10666J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	238.48	38.80	Ibavyr [IX]

### ■ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

#### Authority required (STREAMLINED)

**5940**

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

## valaciclovir 500 mg tablet, 30

5480K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.35	26.56	<sup>a</sup> APO-Valaciclovir [TX] <sup>a</sup> Shilova 500 [DO]	<sup>a</sup> Chem mart Valaciclovir [CH] <sup>a</sup> Terry White Chemists Valaciclovir [TW]
						<sup>a</sup> Vaclovir [AF] <sup>a</sup> Valaciclovir generichealth [GQ] <sup>a</sup> Valaciclovir SZ [HX] <sup>a</sup> Zelitrex [RF]	<sup>a</sup> Valaciclovir AN [EA] <sup>a</sup> Valaciclovir RBX [RA] <sup>a</sup> Valacor 500 [CR]
			<sup>b</sup> 2.26	27.61	26.56	<sup>a</sup> Valtrex [RW]	

### ■ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

#### Authority required (STREAMLINED)

**5961**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 30**

8134D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.35	26.56	<sup>a</sup> APO-Valaciclovir [TX]	<sup>a</sup> Chem mart Valaciclovir [CH]
						<sup>a</sup> Shilova 500 [DO]	<sup>a</sup> Terry White Chemists Valaciclovir [TW]
						<sup>a</sup> Vaclovir [AF]	<sup>a</sup> Valaciclovir AN [EA]
						<sup>a</sup> Valaciclovir generichealth [GQ]	<sup>a</sup> Valaciclovir RBX [RA]
						<sup>a</sup> Valaciclovir Sandoz [SZ]	<sup>a</sup> Valaciclovir SZ [HX]
						<sup>a</sup> Valacor 500 [CR]	<sup>a</sup> Zelitrex [RF]
			<sup>b</sup> 2.26	27.61	26.56	<sup>a</sup> Valtrex [RW]	

▪ **VALACICLOVIR**

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

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

**Authority required (STREAMLINED)**

**5960**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 10**

8133C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*20.59	21.80	<sup>a</sup> APO-Valaciclovir [TX]	<sup>a</sup> Vaclovir [AF]
						<sup>a</sup> Valaciclovir AN [EA]	<sup>a</sup> Valaciclovir Sandoz [SZ]
						<sup>a</sup> Zelitrex [RF]	
						<sup>a</sup> Valtrex [RW]	
			<sup>b</sup> 2.26	*22.85	21.80	<sup>a</sup> Valtrex [RW]	

▪ **VALACICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

**5962**

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)**

**5968**

Herpes zoster ophthalmicus

**valaciclovir 500 mg tablet, 42**

8064K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	31.05	32.26	<sup>a</sup> APO-Valaciclovir [TX]	<sup>a</sup> Chem mart Valaciclovir [CH]
						<sup>a</sup> Terry White Chemists Valaciclovir [TW]	<sup>a</sup> Vaclovir [AF]
						<sup>a</sup> Valaciclovir AN [EA]	<sup>a</sup> Valaciclovir generichealth [GQ]
						<sup>a</sup> Valaciclovir RBX [RA]	<sup>a</sup> Valaciclovir Sandoz [SZ]
						<sup>a</sup> Valacor 500 [CR]	<sup>a</sup> Zelitrex [RF]
						<sup>a</sup> Valtrex [RW]	
			<sup>b</sup> 2.26	33.31	32.26	<sup>a</sup> Valtrex [RW]	

*Other antivirals*

▪ **DACLATASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**daclatasvir 30 mg tablet, 28**

10645G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	7816.19	38.80	Daklinza [BQ]

**daclatasvir 60 mg tablet, 28**

10642D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	7816.19	38.80	Daklinza [BQ]

▪ **DACLATASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**daclatasvir 30 mg tablet, 28**

10671P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	7816.19	38.80	Daklinza [BQ]

**daclatasvir 60 mg tablet, 28**

10659B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	7816.19	38.80	Daklinza [BQ]

▪ **GRAZOPREVIR + ELBASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

11011M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	21149.52	38.80	Zepatier [MK]

▪ **GRAZOPREVIR + ELBASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

11021C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	21149.52	38.80	Zepatier [MK]

▪ **LEDIPASVIR + SOFOSBUVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10628J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	22216.19	38.80	Harvoni [GI]

▪ **LEDIPASVIR + SOFOSBUVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10668L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	22216.19	38.80	Harvoni [GI]

▪ **LEDIPASVIR + SOFOSBUVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10670N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22216.19	38.80	Harvoni [GI]

▪ **PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28**

10766P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	14002.65	38.80	Viekira Pak [VE]

▪ **PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (& dasabuvir 250 mg tablet [56] (& ribavirin 600 mg tablet [56], 1 pack**

10747P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14002.65	38.80	Viekira Pak-RBV [VE]

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (& dasabuvir 250 mg tablet [56] (& ribavirin 200 mg tablet [168], 1 pack**

10771X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14002.65	38.80	Viekira Pak-RBV [VE]

▪ **PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (& dasabuvir 250 mg tablet [56] (& ribavirin 600 mg tablet [56], 1 pack**

10769T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	14002.65	38.80	Viekira Pak-RBV [VE]

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (& dasabuvir 250 mg tablet [56] (& ribavirin 200 mg tablet [168], 1 pack**

10772Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	14002.65	38.80	Viekira Pak-RBV [VE]

▪ **SOFOSBUVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

10624E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	19447.27	38.80	Sovaldi [GI]

▪ **SOFOSBUVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

10657X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19447.27	38.80	Sovaldi [GI]

▪ **SOFOSBUVIR + VELPATASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

11147Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	22216.19	38.80	Epclusa [GI]

▪ **VACCINES**

**BACTERIAL VACCINES**

*Pneumococcal vaccines*

▪ **PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES**

**Restricted benefit**

Prophylaxis of pneumococcal infection

**Clinical criteria:**

- Patient must have undergone a splenectomy.

**Population criteria:**

- Patient must be aged 2 years or older.

**Restricted benefit**

Prophylaxis of pneumococcal infection

**Clinical criteria:**

- Patient must have Hodgkin's disease; OR
- Patient must have a high risk of contracting pneumococcal infections.

**pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL vial**

1903E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	48.85	38.80	Pneumovax 23 [CS]

**pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL syringe**

10210J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	48.85	38.80	Pneumovax 23 [CS]

*Tetanus vaccines*

▪ **DIPHTHERIA TOXOID + TETANUS TOXOID**

**Note** For immunisation of adults and children aged greater than or equal to 8 years.

**diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes**

8783G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	70.61	38.80	ADT Booster [CS]

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

General

## diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials

10261C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	136.39	38.80	MassBiologics tetanus and diphtheria toxoids adsorbed [CS]

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### ANTINEOPLASTIC AGENTS

#### ALKYLATING AGENTS

##### *Nitrogen mustard analogues*

### CHLORAMBUCIL

#### chlorambucil 2 mg tablet, 25

1163F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*138.39	38.80	Leukeran [AS]

### CYCLOPHOSPHAMIDE

#### cyclophosphamide 50 mg tablet, 50

10026Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	77.48	38.80	Endoxan [BX]

#### cyclophosphamide 50 mg tablet, 50

1266P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	31.64	32.85	Cycloblastin [ZX]

### MELPHALAN

#### melphalan 2 mg tablet, 25

2547C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	71.85	38.80	Alkeran [AS]

##### *Alkyl sulfonates*

### BUSULFAN

#### busulfan 2 mg tablet, 100

1128J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	88.31	38.80	Myleran [AS]

##### *Nitrosoureas*

### CARMUSTINE

**Note** Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

#### Restricted benefit

Glioblastoma multiforme

#### Clinical criteria:

- The condition must be suspected or confirmed at the time of initial surgery.

#### carmustine 7.7 mg implant, 8

8898H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16672.83	38.80	Gladel [EI]

##### *Other alkylating agents*

### TEMOZOLOMIDE

#### temozolomide 20 mg capsule, 5

8379B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	37.85	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temizole 20 [QA] <sup>a</sup> Temolide [JU] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Alphapharm [AF]

#### temozolomide 5 mg capsule, 5

8378Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	20.20	21.41	<sup>a</sup> APO-Temozolomide [TX]	<sup>a</sup> Orion Temozolomide [ON]

General

- <sup>a</sup> Temizole 5 [QA]
- <sup>a</sup> Temolide [JU]
- <sup>a</sup> Temodal [MK]
- <sup>a</sup> Temozolomide Alphapharm [AF]
- <sup>a</sup> Temozolomide Amneal [ED]

**temozolomide 140 mg capsule, 5**

9362R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	169.23	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temizole 140 [QA] <sup>a</sup> Temolide [JU] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Alphapharm [AF]

**temozolomide 100 mg capsule, 5**

8380C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	125.76	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temizole 100 [QA] <sup>a</sup> Temolide [JU] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Alphapharm [AF]

**temozolomide 180 mg capsule, 5**

2438H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	202.99	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temolide [JU]

**temozolomide 250 mg capsule, 5**

8381D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	286.79	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temizole 250 [QA] <sup>a</sup> Temolide [JU] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Alphapharm [AF]

▪ **TEMOZOLOMIDE**

**Note** Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

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

**Restricted benefit**

Glioblastoma multiforme

**Treatment criteria:**

- Patient must be undergoing concomitant radiotherapy.

**temozolomide 20 mg capsule, 5**

8820F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*91.36	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temizole 20 [QA] <sup>a</sup> Temolide [JU] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Alphapharm [AF]

**temozolomide 5 mg capsule, 5**

8819E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*38.41	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temizole 5 [QA] <sup>a</sup> Temolide [JU] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Alphapharm [AF]

**temozolomide 140 mg capsule, 5**

9361Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*495.82	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temizole 140 [QA] <sup>a</sup> Temolide [JU] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Alphapharm [AF]

**temozolomide 100 mg capsule, 5**

8821G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*360.85	38.80	<sup>a</sup> APO-Temozolomide [TX]	<sup>a</sup> Orion Temozolomide [ON]

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

<sup>a</sup> Temizole 100 [QA]  
<sup>a</sup> Temolide [JU]  
<sup>a</sup> Temozolomide Amneal [ED]  
<sup>a</sup> Temodal [MK]  
<sup>a</sup> Temozolomide Alphapharm [AF]

## temozolomide 180 mg capsule, 5

10062N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*599.41	38.80	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temodal [MK] <sup>a</sup> Temozolomide Amneal [ED]	<sup>a</sup> Orion Temozolomide [ON] <sup>a</sup> Temolide [JU]

## ANTIMETABOLITES

### Folic acid analogues

#### ■ METHOTREXATE

##### methotrexate 10 mg tablet, 15

2272N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	23.19	24.40	Methoblastin [PF]

##### methotrexate 2.5 mg tablet, 30

1622J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	16.92	18.13	Methoblastin [PF]

##### methotrexate 5 mg/2 mL injection, 5 x 2 mL vials

2396D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	39.94	38.80	Hospira Pty Limited [PF]

#### ■ METHOTREXATE

##### Restricted benefit

Patients requiring doses greater than 20 mg per week

##### methotrexate 10 mg tablet, 50

1623K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	51.41	38.80	Methoblastin [PF]

#### ■ METHOTREXATE

**Note** For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

##### METHOTREXATE Injection 50 mg in 2 mL, 1

1818Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*38.50	38.80	<sup>a</sup> Methotrexate Accord [OD]

##### methotrexate 50 mg/2 mL injection, 5 x 2 mL vials

2395C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	38.51	38.80	<sup>a</sup> Hospira Pty Limited [PF]

### Purine analogues

#### ■ FLUDARABINE

##### fludarabine phosphate 10 mg tablet, 20

9184J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	930.60	38.80	Fludara [GZ]

#### ■ MERCAPTOPURINE

##### mercaptopurine 20 mg/mL oral liquid, 100 mL

10214N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	435.07	38.80	Allmercap [LM]

##### mercaptopurine 50 mg tablet, 25

1598D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*243.07	38.80	Purinethol [AS]

### THIOGUANINE

#### thioguanine 40 mg tablet, 25

1233X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	219.57	38.80	Lanvis [AS]

#### Pyrimidine analogues

### CAPECITABINE

#### capecitabine 500 mg tablet, 120

8362D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	111.51	38.80	<sup>a</sup> Capecitabine Alphapharm [AF]	<sup>a</sup> Capecitabine AN [EA]
						<sup>a</sup> Capecitabine Apotex [TX]	<sup>a</sup> Capecitabine-DRLA [RZ]
						<sup>a</sup> Capecitabine MYX [OC]	<sup>a</sup> Capecitabine Sandoz [SZ]
						<sup>a</sup> Xelabine [QA]	<sup>a</sup> Xelocitabine [JU]
			<sup>b</sup> 5.04	116.55	38.80	<sup>a</sup> Xeloda [RO]	

#### capecitabine 150 mg tablet, 60

8361C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	27.29	28.50	<sup>a</sup> Capecitabine AN [EA]	<sup>a</sup> Capecitabine-DRLA [RZ]
						<sup>a</sup> Capecitabine MYX [OC]	<sup>a</sup> Xelabine [QA]
						<sup>a</sup> Xelocitabine [JU]	

### PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

#### Vinca alkaloids and analogues

### VINORELBINE

#### Authority required

Advanced breast cancer

#### Clinical criteria:

- Patient must have failed standard prior therapy, which includes an anthracycline.

#### Authority required

Locally advanced or metastatic non-small cell lung cancer

#### vinorelbine 20 mg capsule, 1

9009E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	20	2	..	*1570.15	38.80	Navelbine [FB]

#### vinorelbine 30 mg capsule, 1

9010F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	16	2	..	*1878.83	38.80	Navelbine [FB]

#### Podophyllotoxin derivatives

### ETOPOSIDE

#### etoposide 50 mg capsule, 20

1396L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	440.03	38.80	Vepesid [BQ]

#### etoposide 100 mg capsule, 10

1389D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	383.92	38.80	Vepesid [BQ]

### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

#### Anthracyclines and related substances

### IDARUBICIN

#### Restricted benefit

Acute myelogenous leukaemia (AML)

#### idarubicin hydrochloride 10 mg capsule, 1

2448W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*490.51	38.80	Zavedos [PF]

#### idarubicin hydrochloride 5 mg capsule, 1

2446R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*306.61	38.80	Zavedos [PF]

## OTHER ANTINEOPLASTIC AGENTS

## Monoclonal antibodies

## ■ RITUXIMAB

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

**Authority required (STREAMLINED)****6011**

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, **AND**
- Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

10709P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	2853.30	38.80	Mabthera SC [RO]

## ■ RITUXIMAB

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

**Authority required (STREAMLINED)****5998**

Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

**Clinical criteria:**

- The treatment must be for re-induction treatment purposes only, **AND**
- The condition must have relapsed or be refractory to treatment, **AND**
- Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

**Authority required (STREAMLINED)****6039**

Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

**Clinical criteria:**

- The treatment must be for re-induction treatment purposes only, **AND**
- The condition must have relapsed or be refractory to treatment, **AND**
- Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

10703H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2853.30	38.80	Mabthera SC [RO]

## ■ RITUXIMAB

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

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

**Authority required (STREAMLINED)****6161**

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, **AND**
- Patient must not have received bendamustine induction therapy, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

10742J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	2853.30	38.80	Mabthera SC [RO]

**▪ RITUXIMAB**

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

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

**Authority required (STREAMLINED)****6309**

Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

**Authority required (STREAMLINED)****6162**

Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy

Treatment Phase: Induction treatment

**Clinical criteria:**

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

10719E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	2853.30	38.80	Mabthera SC [RO]

**▪ TRASTUZUMAB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

**Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

**Authority required**

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

**Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**

- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

#### trastuzumab 600 mg/5 mL injection, 5 mL vial

10682F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2945.37	38.80	Herceptin SC [RO]

#### ▪ TRASTUZUMAB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

##### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

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

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**

- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

##### Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

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

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**

- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

#### trastuzumab 600 mg/5 mL injection, 5 mL vial

10721G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2945.37	38.80	Herceptin SC [RO]

#### ▪ TRASTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the patient has Stage IV disease.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10798H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2945.37	38.80	Herceptin SC [RO]

▪ **TRASTUZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, authority approval will be granted for a new loading dose.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10803N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2945.37	38.80	Herceptin SC [RO]

▪ **TRASTUZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10825R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2945.37	38.80	Herceptin SC [RO]

**Protein kinase inhibitors****■ AXITINIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**axitinib 5 mg tablet, 28**

10556N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*5189.53	38.80	Inlyta [PF]

**axitinib 1 mg tablet, 28**

10539Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1120.45	38.80	Inlyta [PF]

**■ AXITINIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

**axitinib 5 mg tablet, 28**

10540R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*5189.53	38.80	Inlyta [PF]

**axitinib 1 mg tablet, 28**

10572K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*1120.45	38.80	Inlyta [PF]

**■ CERITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

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

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**Authority required**

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

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

**Authority required**

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

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 February 2017, **AND**
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

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

**ceritinib 150 mg capsule, 3 x 50**

11056X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7277.82	38.80	Zykadia [NV]

▪ **COBIMETINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6839**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must not have progressive disease when treated with a BRAF inhibitor.

**cobimetinib 20 mg tablet, 63**

11074W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	8187.55	38.80	Cotellic [RO]

▪ **COBIMETINIB**

**Note** A patient who has had progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6803**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**cobimetinib 20 mg tablet, 63**

11075X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8187.55	38.80	Cotellic [RO]

**■ CRIZOTINIB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

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

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

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

(1) a completed authority prescription form; and

(2) a completed ALK-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ALK gene rearrangement in tumour material by FISH testing.

**Authority required**

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

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**crizotinib 250 mg capsule, 60**

10322G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7277.82	38.80	Xalkori [PF]

**crizotinib 200 mg capsule, 60**

10323H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7277.82	38.80	Xalkori [PF]

**■ DABRAFENIB**

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****6044**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS subsidised therapy; OR

- Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**dabrafenib 75 mg capsule, 120**

2846T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	8761.69	38.80	Tafinlar [NV]

**dabrafenib 50 mg capsule, 120**

2963Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	5890.97	38.80	Tafinlar [NV]

▪ **DABRAFENIB**

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6013**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**dabrafenib 75 mg capsule, 120**

10003L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8761.69	38.80	Tafinlar [NV]

**dabrafenib 50 mg capsule, 120**

2954L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5890.97	38.80	Tafinlar [NV]

▪ **DASATINIB**

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be a primary diagnosis, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and
- (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
- (4) a signed patient acknowledgement form

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) demonstration of continued response to treatment as evidenced by either: (a) a major cytogenetic response [see Note explaining requirements]; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR

- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Subsequent authority applications for continuing therapy with this drug may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### dasatinib 20 mg tablet, 60

1354G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2951.16	38.80	Sprycel [BQ]

#### dasatinib 50 mg tablet, 60

1381Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4764.09	38.80	Sprycel [BQ]

#### dasatinib 70 mg tablet, 60

1415L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5862.66	38.80	Sprycel [BQ]

#### dasatinib 100 mg tablet, 30

1416M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4764.09	38.80	Sprycel [BQ]

### ■ DASATINIB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate is not approved for use in second or third line treatment. Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent. Nilotinib is not approved for patients in blast crisis. 1. Initial second line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response. 2. Initial third line treatment Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent. From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis. 3. Continuing treatment for second and third line treatment All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows: (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained. During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent. 4. Authority approval requirements. Response criteria to initial treatment with dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 5. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 6. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)  
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have failed PBS-subsidised first line treatment with this drug for this condition, **AND**
  - Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
  - Patient must have failed an adequate trial of PBS-subsidised first line treatment with nilotinib for this condition; OR
  - Patient must have experienced intolerance, not a failure of response, to PBS-subsidised second line treatment with nilotinib for this condition, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Failure of an adequate trial of imatinib or nilotinib is defined as:(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); ORBlast crisis is defined as either:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or(2) Extramedullary involvement other than spleen and liver; OR(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and(c) a signed patient acknowledgement; and(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

**Authority required**

Chronic Myeloid Leukaemia (CML)  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS- subsidised second line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and (3) demonstration of continued response to treatment as evidenced by either: (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report need be provided; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report need be provided.

**dasatinib 20 mg tablet, 60**

2478K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2951.16	38.80	Sprycel [BQ]

**dasatinib 50 mg tablet, 60**

2482P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4764.09	38.80	Sprycel [BQ]

**dasatinib 70 mg tablet, 60**

2485T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5862.66	38.80	Sprycel [BQ]

**dasatinib 100 mg tablet, 30**

9342Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4764.09	38.80	Sprycel [BQ]

**■ DASATINIB**

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

**Note** No applications for increased repeats will be authorised.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoietic stem cell transplantation if applicable, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of treatment is defined as either:

- Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;
- Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;
- Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation. Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

- a completed authority prescription form; and
- a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
- a signed patient acknowledgement; and
- a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have been treated for this condition prior to 1 December 2007, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed an allogeneic haemopoietic stem cell transplantation if applicable, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
- (c) a signed patient acknowledgement; and
- (d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not have progressed, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **dasatinib 20 mg tablet, 60**

9125G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2951.16	38.80	Sprycel [BQ]

#### **dasatinib 50 mg tablet, 60**

9126H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4764.09	38.80	Sprycel [BQ]

#### **dasatinib 70 mg tablet, 60**

9127J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5862.66	38.80	Sprycel [BQ]

#### **dasatinib 100 mg tablet, 30**

9343R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4764.09	38.80	Sprycel [BQ]

### ■ ERLOTINIB

#### **Authority required**

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

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, **AND**
- Patient must not have progressive disease.

#### **Population criteria:**

- Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
- Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

#### **erlotinib 100 mg tablet, 30**

10019H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1173.53	38.80	Tarceva [RO]

#### **erlotinib 25 mg tablet, 30**

10028T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	329.57	38.80	Tarceva [RO]

**erlotinib 150 mg tablet, 30**

10025P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1433.50	38.80	Tarceva [RO]

▪ **ERLOTINIB**

**Authority required**

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

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**Authority required**

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

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**erlotinib 100 mg tablet, 30**

10020J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1173.53	38.80	Tarceva [RO]

**erlotinib 25 mg tablet, 30**

10022L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	329.57	38.80	Tarceva [RO]

**erlotinib 150 mg tablet, 30**

10014C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1433.50	38.80	Tarceva [RO]

▪ **EVEROLIMUS**

**Note** Special Pricing Arrangements apply.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been treated with PBS-subsidised everolimus for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

**everolimus 2.5 mg tablet, 30**

2818H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1404.57	38.80	Afinitor [NV]

**▪ EVEROLIMUS**

**Note** Special Pricing Arrangements apply.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been treated with PBS-subsidised everolimus for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

**Authority required**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, **AND**
- The treatment must be in combination with exemestane.

**Population criteria:**

- Patient must not be pre-menopausal.

**Note** Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**everolimus 10 mg tablet, 30**

2985D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5279.52	38.80	Afinitor [NV]

**everolimus 5 mg tablet, 30**

2819J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2714.52	38.80	Afinitor [NV]

**▪ EVEROLIMUS**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

**everolimus 10 mg tablet, 30**

10135K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5279.52	38.80	Afinitor [NV]

**everolimus 5 mg tablet, 30**

10131F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2714.52	38.80	Afinitor [NV]

**■ EVEROLIMUS**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**
  - Patient must have a WHO performance status of 2 or less, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

**everolimus 10 mg tablet, 30**

10132G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5279.52	38.80	Afinitor [NV]

**everolimus 5 mg tablet, 30**

10133H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2714.52	38.80	Afinitor [NV]

**■ GEFITINIB****Authority required**

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

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**

- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**Authority required**

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

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

**gefitinib 250 mg tablet, 30**

8769M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1433.50	38.80	Iressa [AP]

▪ **IBRUTINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

- Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;
- Age is 70 years or older;
- Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;
- History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;
- Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**ibrutinib 140 mg capsule, 90**

11213E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8782.81	38.80	Imbruvica [JC]

▪ **IMATINIB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:
  - (i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and
  - (ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and
  - (iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib. Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Applications for continuing treatment may be made by telephone

**Note** For the following diseases, written authority is required at initiation and for continuation:

- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

**imatinib 400 mg tablet, 30**

9112N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	Glivec [AF]

**imatinib 100 mg tablet, 60**

9111M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	Glivec [AF]

**■ IMATINIB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, **AND**

• The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and
- (d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and
- (e) details of the prior therapy trialled and the response; and
- (f) a signed patient acknowledgement

**Authority required**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the full blood examination report which demonstrates a complete haematological response; and
- (d) a statement that the disease has not progressed on imatinib therapy

**imatinib 400 mg tablet, 30**

9177B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg tablet, 60**

9176Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg capsule, 60**

10918P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg capsule, 30**

10939R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

▪ **IMATINIB**

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

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

Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFR fusion gene; and
- (d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and
- (e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
- (f) a signed patient acknowledgement

**Authority required**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and
- (d) a statement that the disease has not progressed on imatinib therapy

**imatinib 400 mg tablet, 30**

9175X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg tablet, 60**

9174W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg capsule, 60**

10941W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg capsule, 30**

10925B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

▪ **IMATINIB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

#### **Authority required**

Dermatofibrosarcoma protuberans  
Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be unresectable; OR
  - The condition must be locally recurrent; OR
  - The condition must be metastatic, **AND**
  - The treatment must not exceed a maximum dose of 800 mg per day.
- (1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and
- (2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and
- (3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:

- a completed authority prescription form; and
- a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- a signed patient acknowledgement

#### **Authority required**

Dermatofibrosarcoma protuberans  
Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- a statement that the disease has not progressed on imatinib therapy

#### **imatinib 400 mg tablet, 30**

9173T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

#### **imatinib 100 mg tablet, 60**

9172R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

#### **imatinib 100 mg capsule, 60**

10942X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

#### **imatinib 400 mg capsule, 30**

10933K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

#### ▪ **IMATINIB**

#### **Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

Applications for authorisation of initial treatment must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application.

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270.

**Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

Applications for continuing therapy may be made by telephone.

**Note** Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**imatinib 400 mg tablet, 30**

5444M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2486.52	38.80	Glivec [AF]

**imatinib 100 mg tablet, 60**

5443L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1286.58	38.80	Glivec [AF]

▪ **IMATINIB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

#### **Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFR fusion gene; and
- (d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and
- (e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
- (f) details of prior treatment trialled and the response; and
- (g) a signed patient acknowledgement

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

#### **Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the full blood examination report which demonstrates a complete haematological response; and
- (d) a statement that the disease has not progressed on imatinib therapy

**Note** No applications for increased repeats will be authorised.

#### **imatinib 400 mg tablet, 30**

9179D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> Glivec [AF]	<sup>a</sup> IMATINIB RBX [RA]

#### **imatinib 100 mg tablet, 60**

9178C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> Glivec [AF]	<sup>a</sup> IMATINIB RBX [RA]

#### **imatinib 100 mg capsule, 60**

10940T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

#### **imatinib 400 mg capsule, 30**

10921T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

### ■ IMATINIB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond

#### 2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

#### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and (4) a signed patient acknowledgement form

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
 Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)  
 Treatment Phase: First Continuing

**Clinical criteria:**

- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a response to treatment as evidenced by either:
  - (a) a major cytogenetic response [see Note explaining requirements]; or
  - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)  
 Treatment Phase: Subsequent continuing

**Clinical criteria:**

- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Second and subsequent authority applications for continuing therapy with imatinib mesilate may be made on the telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**imatinib 400 mg tablet, 30**

9114Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	2486.52	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg tablet, 60**

9113P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1286.58	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg capsule, 60**

10915L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1286.58	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg capsule, 30**

10916M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	2486.52	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

▪ **IMATINIB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and  
 (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and  
 (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**imatinib 400 mg tablet, 30**

9116T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg tablet, 60**

9115R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg capsule, 60**

10920R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg capsule, 30**

10935M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**■ IMATINIB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**

- The treatment must be for induction and consolidation therapy, **AND**
  - The treatment must be in combination with chemotherapy.
- The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
  - (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
  - (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
  - (d) a signed patient acknowledgement

**Authority required**

Acute lymphoblastic leukaemia  
Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
  - The condition must have the transcript BCR-ABL, **AND**
  - Patient must have previously received treatment with this drug for this condition under Imatinib Compassionate Program.
- The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

**Authority required**

Acute lymphoblastic leukaemia  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy.

Imatinib is available with a lifetime maximum of 24 months for continuing treatment with imatinib therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

**Note** Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**imatinib 400 mg tablet, 30**

9124F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg tablet, 60**

9123E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

**imatinib 100 mg capsule, 60**

10924Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.58	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg capsule, 30**

10917N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2486.52	38.80	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [EA] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

▪ **LAPATINIB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer  
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must have received prior therapy with a taxane for at least 3 cycles; OR
- Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must have progressed following treatment with pertuzumab and trastuzumab in combination, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:
  - (i) a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease;
  - (ii) date of last treatment with a taxane and total number of cycles;
  - (iii) a copy of the signed patient acknowledgement form;
  - (iv) dates of treatment with trastuzumab and pertuzumab; and
  - (v) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

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

**lapatinib 250 mg tablet, 70**

9148L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*3228.57	38.80	Tykerb [NV]

▪ **LENVATINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6604**

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have symptomatic progressive disease prior to treatment; OR
- Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, **AND**
- Patient must have thyroid stimulating hormone adequately repressed, **AND**
- Patient must be one in whom surgery is inappropriate, **AND**
- Patient must not be a candidate for radiotherapy with curative intent, **AND**
- Patient must have a WHO performance status of 2 or less.

Radioactive iodine refractory is defined as:

- a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- progression within 12 months of a single RAI treatment; or
- progression after two RAI treatments administered within 12 months of each other.

**Authority required (STREAMLINED)**

**6578**

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Authority required (STREAMLINED)**

**6577**

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have thyroid stimulating hormone adequately repressed.

**lenvatinib 4 mg capsule, 30**

10952K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3304.52	38.80	Lenvima [EI]

**lenvatinib 10 mg capsule, 30**

10965D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6459.53	38.80	Lenvima [EI]

▪ **NILOTINIB**

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be a primary diagnosis, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved. Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and (4) a signed patient acknowledgement form. The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment - Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**

- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) demonstration of continued response to treatment as evidenced by either:(a) a major cytogenetic response [see Note explaining requirements]; or(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Subsequent authority applications for continuing therapy with this drug may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**NILOTINIB Capsule 150 mg (as hydrochloride monohydrate), 120**

1309X

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	4254.95	38.80	Tasigna [NV]

▪ **NILOTINIB**

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

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

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with dasatinib for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or dasatinib is defined as:(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral

white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy. Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and (c) a signed patient acknowledgement; and (d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and (e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate is not approved for use in second or third line treatment. Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent. Nilotinib is not approved for patients in blast crisis.

- Initial second line treatment: From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.
- Initial third line treatment: Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent. From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.
- Continuing treatment for second and third line treatment: All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows: (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained. During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.
- Authority approval requirements: Response criteria to initial treatment with dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
- Definitions of response: A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
- Definitions of loss of response: Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and (3) demonstration of continued response to treatment as evidenced by either: (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

#### **NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120**

9171Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5589.01	38.80	Tasigna [NV]

**■ NINTEDANIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must not have an acute respiratory infection at the time of FVC testing.

Applications for authorisation of initial treatment must be in writing and must include:

- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

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

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 3 - Grandfathering treatment

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2017, **AND**
- The condition must have been diagnosed through a multidisciplinary team, **AND**
- Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must not have an acute respiratory infection at the time of FVC testing.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

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

Applications for authorisation of initial treatment must be in writing and must include:

- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**nintedanib 100 mg capsule, 60**

11100F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1752.64	38.80	Ofev [BY]

**nintedanib 150 mg capsule, 60**

11106M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3387.12	38.80	Ofev [BY]

▪ **PAZOPANIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- Patient must not have received prior treatment with an angiogenesis inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:

- adipocytic soft tissue sarcoma;
- gastrointestinal stromal tumour (GIST);
- rhabdomyosarcoma other than alveolar or pleomorphic;
- chondrosarcoma;
- osteosarcoma;
- Ewings tumour/primitive neuroectodermal tumour;
- dermofibromatosis sarcoma protuberans;
- inflammatory myofibroblastic sarcoma;
- malignant mesothelioma;
- mixed mesodermal tumour of the uterus.

The authority application must be made in writing.

**pazopanib 400 mg tablet, 60**

10041L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4676.80	38.80	Votrient [NV]

**pazopanib 200 mg tablet, 90**

10042M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3544.98	38.80	Votrient [NV]

▪ **PAZOPANIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
  - Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Applications for continuing therapy may be made by telephone.

**pazopanib 400 mg tablet, 60**

10043N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4676.80	38.80	Votrient [NV]

**pazopanib 200 mg tablet, 90**

10047T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3544.98	38.80	Votrient [NV]

▪ **PAZOPANIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
  - Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
  - Patient must require dose adjustment, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Applications for continuing therapy may be made by telephone.

**pazopanib 400 mg tablet, 30**

10052C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2413.16	38.80	Votrient [NV]

**pazopanib 200 mg tablet, 30**

10054E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1248.61	38.80	Votrient [NV]

▪ **PAZOPANIB**

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note** Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:  
 Complete response (CR) is disappearance of all target lesions.  
 Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.  
 Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.  
 Stable disease (SD) is small changes that do not meet above criteria.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)  
 Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**pazopanib 400 mg tablet, 30**

2201W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2413.16	38.80	Votrient [NV]

**pazopanib 200 mg tablet, 30**

2232L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1248.61	38.80	Votrient [NV]

▪ **PAZOPANIB**

**Note** No increase in the maximum quantity or number of units may be authorised.  
**Note** No increase in the maximum number of repeats may be authorised.  
**Note** Special Pricing Arrangements apply.  
**Note** Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.  
**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)  
 Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.  
 Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**pazopanib 400 mg tablet, 60**

2030W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4676.80	38.80	Votrient [NV]

**pazopanib 200 mg tablet, 90**

2029T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3544.98	38.80	Votrient [NV]

▪ **PAZOPANIB**

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.  
**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)  
 Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note** Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:  
 Complete response (CR) is disappearance of all target lesions.  
 Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.  
 Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.  
 Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have been receiving treatment with pazopanib prior to 1 October 2012, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**pazopanib 400 mg tablet, 60**

2035D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4676.80	38.80	Votrient [NV]

**pazopanib 200 mg tablet, 90**

2034C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3544.98	38.80	Votrient [NV]

■ **PONATINIB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.

1. Continuing treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

2. Authority approval requirements.

Response criteria to initial treatment with ponatinib:

For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib, nilotinib or ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

3. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

4. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have failed an adequate trial of dasatinib; OR
- Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have failed an adequate trial of nilotinib; OR
- Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR
- Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:

1. Lack of response to dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR
- Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR
  - Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR
  - Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR
  - Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

- Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
- Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
- Peripheral basophils greater than or equal to 20%; or
- Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
- Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

- Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
- Extramedullary involvement other than spleen and liver.

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

- a completed authority prescription form;
- a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form;
- a signed patient acknowledgement;
- a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report, which should be within the previous 6 months, needs to be provided); and
- where there has been a loss of response to dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed an adequate trial of imatinib; OR
- Patient must have failed an adequate trial of dasatinib; OR
- Patient must have failed an adequate trial of nilotinib.

Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:

- Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:
  - failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or
  - failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
  - failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR
- Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR
- Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR
- Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR
- Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

- Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
- Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
- Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

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

1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form; and
3. a signed patient acknowledgement; and
4. a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale and evidence of the T315I mutation. (The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided); and
5. where there has been a loss of response to imatinib or dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to ponatinib within 18 months of commencement and at no greater than 12 month intervals thereafter.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia Continuing PBS authority application Supporting information form; and
3. demonstration of continued response to treatment as evidenced by either:
  - (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or
  - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

**ponatinib 15 mg tablet, 60**

10520Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5758.13	38.80	Iclusig [TS]

**ponatinib 45 mg tablet, 30**

10530F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6477.57	38.80	Iclusig [TS]

▪ **PONATINIB**

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, **AND**
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;
  2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;
  3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.
- Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and

3. a signed patient acknowledgement; and

4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **ponatinib 15 mg tablet, 60**

10523W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5758.13	38.80	Iclusig [TS]

#### **ponatinib 45 mg tablet, 30**

10524X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6477.57	38.80	Iclusig [TS]

#### **▪ RUXOLITINIB**

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

#### **Authority required**

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

#### **ruxolitinib 20 mg tablet, 56**

10617T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5149.52	38.80	Jakavi [NV]

**ruxolitinib 5 mg tablet, 56**

10616R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*5149.53	38.80	Jakavi [NV]

**ruxolitinib 15 mg tablet, 56**

10615Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5149.52	38.80	Jakavi [NV]

**ruxolitinib 10 mg tablet, 56**

10927D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5149.52	38.80	Jakavi [NV]

**▪ RUXOLITINIB**

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Programs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority required**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

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

- (1) A completed authority prescription form; and
- (2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
  - (a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
  - (b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority required**

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

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

- (1) A completed authority prescription form; and
- (2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
  - a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis;
  - b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and
  - c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

**ruxolitinib 20 mg tablet, 56**

10618W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5149.52	38.80	Jakavi [NV]

**ruxolitinib 5 mg tablet, 56**

10614P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*5149.53	38.80	Jakavi [NV]

**ruxolitinib 15 mg tablet, 56**

10619X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5149.52	38.80	Jakavi [NV]

**ruxolitinib 10 mg tablet, 56**

10913J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5149.52	38.80	Jakavi [NV]

**▪ SORAFENIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.  
 Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.  
 Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sorafenib 200 mg tablet, 60**

10226F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6144.71	38.80	Nexavar [BN]

▪ **SORAFENIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sorafenib 200 mg tablet, 60**

10242C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6144.71	38.80	Nexavar [BN]

▪ **SORAFENIB**

**Note** Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.

Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**4230**

Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma

Treatment Phase: Initial

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A.

**Authority required (STREAMLINED)**

**4234**

Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma

Treatment Phase: Continuing

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

- Patient must have previously been treated with PBS-subsidised sorafenib, **AND**
- Patient must not have progressive disease.

**sorafenib 200 mg tablet, 60**

9380Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6144.71	38.80	Nexavar [BN]

▪ **SUNITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**

- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.

Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**sunitinib 37.5 mg capsule, 28**

10464R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4959.60	38.80	Sutent [PF]

**sunitinib 25 mg capsule, 28**

2959R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3356.15	38.80	Sutent [PF]

**sunitinib 50 mg capsule, 28**

2837H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6563.05	38.80	Sutent [PF]

**sunitinib 12.5 mg capsule, 28**

10004M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1736.75	38.80	Sutent [PF]

▪ **SUNITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have disease progression, **AND**

- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

**sunitinib 37.5 mg capsule, 28**

10473F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4959.60	38.80	Sutent [PF]

**sunitinib 25 mg capsule, 28**

2842N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3356.15	38.80	Sutent [PF]

**sunitinib 50 mg capsule, 28**

10010W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6563.05	38.80	Sutent [PF]

**sunitinib 12.5 mg capsule, 28**

10009T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1736.75	38.80	Sutent [PF]

▪ **SUNITINIB**

- Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.
- Note** Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.
- Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:  
 Complete response (CR) is disappearance of all target lesions.  
 Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.  
 Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.  
 Stable disease (SD) is small changes that do not meet above criteria.
- Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)  
 Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for sunitinib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**sunitinib 37.5 mg capsule, 28**

10459L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	4959.60	38.80	Sutent [PF]

**sunitinib 25 mg capsule, 28**

9421W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	3356.15	38.80	Sutent [PF]

**sunitinib 50 mg capsule, 28**

9422X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6563.05	38.80	Sutent [PF]

**sunitinib 12.5 mg capsule, 28**

9420T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1736.75	38.80	Sutent [PF]

▪ **SUNITINIB**

- Note** Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.
- Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)  
 Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

**sunitinib 37.5 mg capsule, 28**

10504W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4959.60	38.80	Sutent [PF]

**sunitinib 25 mg capsule, 28**

9418Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3356.15	38.80	Sutent [PF]

**sunitinib 50 mg capsule, 28**

9419R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	6563.05	38.80	Sutent [PF]

**sunitinib 12.5 mg capsule, 28**

9417P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1736.75	38.80	Sutent [PF]

**■ SUNITINIB**

**Note** Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

**Note** Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesylate.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

**Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note** Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

**sunitinib 37.5 mg capsule, 28**

10503T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4959.60	38.80	Sutent [PF]

**sunitinib 25 mg capsule, 28**

9489K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3356.15	38.80	Sutent [PF]

**sunitinib 50 mg capsule, 28**

9490L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	6563.05	38.80	Sutent [PF]

**sunitinib 12.5 mg capsule, 28**

9488J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1736.75	38.80	Sutent [PF]

**■ TRAMETINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6778**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must not have had progressive disease when treated with a BRAF inhibitor.

**trametinib 2 mg tablet, 30**

10382K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	8761.69	38.80	Mekinist [NV]

**trametinib 500 microgram tablet, 30**

10403M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*6608.62	38.80	Mekinist [NV]

**■ TRAMETINIB**

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****6752**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**trametinib 2 mg tablet, 30**

10405P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8761.69	38.80	Mekinist [NV]

**trametinib 500 microgram tablet, 30**

10385N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*6608.62	38.80	Mekinist [NV]

**■ VEMURAFENIB**

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****6044**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS subsidised therapy; OR
- Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**vemurafenib 240 mg tablet, 56**

11076Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*8187.59	38.80	Zelboraf [RO]

**■ VEMURAFENIB**

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6013**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**vemurafenib 240 mg tablet, 56**

11081F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*8187.59	38.80	Zelboraf [RO]

*Other antineoplastic agents*

▪ **HYDROXYUREA**

**hydroxyurea 500 mg capsule, 100**

3093T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	71.58	38.80	Hydrea [BQ]

▪ **IDELALISIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage), **AND**
- Patient must be inappropriate for chemo-immunotherapy.

A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:

1. Severe neutropenia defined as absolute neutrophil count of less than or equal to  $1.0 \times 10^9/L$ ; or
2. Severe thrombocytopenia defined as platelet count of less than or equal to  $50 \times 10^9/L$ ; or
3. Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

Full blood count results must be no more than 1 month old at the time of application.

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

- a) A completed authority prescription form;
- b) A completed CLL/SLL PBS Authority Application - Supporting information form; and
- c) Pathology report indicating that the patient can be considered inappropriate for chemo-immunotherapy due to one or more of the following:
  - 1) Recent severe neutropenia; or
  - 2) Recent severe thrombocytopenia; or
  - 3) Presence of 17p chromosomal deletion using fluorescence in situ hybridisation (FISH).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with rituximab, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

**idelalisib 100 mg tablet, 60**

11170X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5367.27	38.80	Zydelig [GI]

**idelalisib 150 mg tablet, 60**

11162L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5367.27	38.80	Zydelig [GI]

**■ IDELALISIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to a prior therapy with rituximab, **AND**
- The condition must be refractory to a prior therapy with an alkylating agent, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

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

- A completed authority prescription form; and
- A completed Refractory follicular B-cell non-Hodgkin's lymphoma PBS Authority Application - Supporting information form which must include date of completion of prior therapies with rituximab and an alkylating agent.

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

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

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

**idelalisib 100 mg tablet, 60**

11171Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5367.27	38.80	Zydelig [GI]

**idelalisib 150 mg tablet, 60**

11165P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5367.27	38.80	Zydelig [GI]

**■ OLAPARIB**

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade serous ovarian cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation. Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

**Authority required**

High grade serous fallopian tube cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation. Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

**Authority required**

High grade serous primary peritoneal cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation. Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

**olaparib 50 mg capsule, 4 x 112**

11034R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6959.52	38.80	Lynparza [AP]

▪ **OLAPARIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6715**

High grade serous ovarian cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

**Authority required (STREAMLINED)**

**6705**

High grade serous fallopian tube cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

**Authority required (STREAMLINED)**

**6716**

High grade serous primary peritoneal cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

**olaparib 50 mg capsule, 4 x 112**

11050N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6959.52	38.80	Lynparza [AP]

▪ **VISMODEGIB**

**Caution** Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 9 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or locally advanced basal cell carcinoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

- A completed authority prescription form; and
- a completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and
- A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
- A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and
- A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and
- A signed patient acknowledgement.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

iii/ Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**

i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or

iii/ Limitations due to cumulative prior radiotherapy dose; or

iv/ Progressive disease despite prior irradiation of locally advanced BCC.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Metastatic or locally advanced basal cell carcinoma  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received an authority prescription for this condition with this drug, **AND**
- The condition must not have progressed, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

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

- a) A completed authority prescription form; and
- b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and
- c) A confirmation statement from the treating doctor that the disease has not progressed; and
- d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**

- i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- iii/ Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**

- i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- ii/ Limitations due to location of tumour; or
- iii/ Limitations due to cumulative prior radiotherapy dose; or
- iv/ Progressive disease despite prior irradiation of locally advanced BCC.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Metastatic or locally advanced basal cell carcinoma  
Treatment Phase: Initial treatment or Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**vismodegib 150 mg capsule, 28**

11070P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7449.52	38.80	Erivedge [RO]

▪ **VORINOSTAT**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

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

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

**Authority required**

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
- Patient must be ineligible for stem cell transplant, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed cutaneous T-cell lymphoma (CTCL) initial PBS Authority Application - Supporting Information Form.

**vorinostat 100 mg capsule, 120**

11138F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4451.64	38.80	Zolinza [MK]

▪ **VORINOSTAT**

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

**Authority required**

Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**vorinostat 100 mg capsule, 120**

11141J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4451.64	38.80	Zolinza [MK]

▪ **ENDOCRINE THERAPY**

**HORMONES AND RELATED AGENTS**

*Progestogens*

▪ **MEDROXYPROGESTERONE**

**Restricted benefit**

Advanced breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**medroxyprogesterone acetate 500 mg tablet, 30**

2728N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	136.20	38.80	Provera [PF]

▪ **MEDROXYPROGESTERONE**

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**Restricted benefit**

Endometrial cancer

**medroxyprogesterone acetate 100 mg tablet, 100**

2725K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	98.72	38.80	Provera [PF]

**medroxyprogesterone acetate 250 mg tablet, 60**

2727M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	136.20	38.80	Provera [PF]

**medroxyprogesterone acetate 200 mg tablet, 60**

2316X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	110.78	38.80	Provera [PF]

**Gonadotropin releasing hormone analogues**

▪ **GOSERELIN**

Restricted benefit

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

**goserelin 10.8 mg implant, 1**

8093Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1050.60	38.80	Zoladex 10.8 Implant [AP]

▪ **GOSERELIN**

Restricted benefit

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

Restricted benefit

Endometriosis

**Clinical criteria:**

- The condition must be visually proven, **AND**
- The treatment must be for the short-term (up to 6 months).

**Note** Only 1 course of not more than 6 months' therapy will be authorised.

Restricted benefit

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

Restricted benefit

Anticipated premature ovarian failure

**Clinical criteria:**

- Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure, **AND**
- Patient must not receive more than 6 months' of treatment for this condition in a lifetime.

**Population criteria:**

- Patient must be pre-menopausal.

**goserelin 3.6 mg implant, 1**

1454M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	308.20	38.80	Zoladex Implant [AP]

▪ **GOSERELIN (&) BICALUTAMIDE**

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

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

Restricted benefit

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack**

9066E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	1467.19	38.80	ZolaCos CP 10.8/50(84) [AP]

**goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack**

9064C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	457.51	38.80	ZolaCos CP 3.6/50 [AP]

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack**

9065D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1189.46	38.80	ZolaCos CP 10.8/50(28) [AP]

**LEUPRORELIN****Restricted benefit**

Central precocious puberty

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR
- Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition.

**leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

10255R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1374.48	38.80	Lucrin Depot Paediatric 30 mg PDS [VE]

**LEUPRORELIN****Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**leuprorelin acetate 30 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack**

8877F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1374.48	38.80	Lucrin Depot 4 Month PDS [VE]

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8708H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1050.60	38.80	Eligard 3 month [TL]

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8707G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	393.95	38.80	Eligard 1 month [TL]

**leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8709J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1374.48	38.80	Eligard 4 month [TL]

**leuprorelin acetate 22.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack**

8876E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1050.60	38.80	Lucrin Depot 3 Month PDS [VE]

**leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack**

10656W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2021.67	38.80	Lucrin Depot 6-Month [VE]

**leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack**

8859G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2021.67	38.80	Eligard 6 month [TL]

**leuprorelin acetate 7.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack**

8875D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	393.95	38.80	Lucrin Depot 7.5mg PDS [VE]

**LEUPRORELIN****Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be aged 10 years or younger (girls) or 11 years or younger (boys), **AND**

- Patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial - grandfather

**Clinical criteria:**

- Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**leuprorelin acetate 30 mg modified release injection [1 syringe] (& inert substance diluent [1 syringe], 1 pack**

10256T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1374.48	38.80	Lucrin Depot Paediatric 30 mg PDS [VE]

**LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (& inert substance diluent [1 syringe] (& bicalutamide 50 mg tablet [28], 1 pack**

10963B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	1123.38	38.80	Bi ELIGARD CP [TL]

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (& inert substance diluent [1 syringe] (& bicalutamide 50 mg tablet [84], 1 pack**

10969H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	1268.94	38.80	Bi ELIGARD CP [TL]

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (& inert substance diluent [1 syringe] (& bicalutamide 50 mg tablet [28], 1 pack**

10962Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	472.21	38.80	Bi ELIGARD CP [TL]

**TRIPTORELIN****Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**triptorelin 3.75 mg injection [1 vial] (& inert substance diluent [2 mL ampoule], 1 pack**

9378N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	393.95	38.80	Diphereline [IS]

**triptorelin 11.25 mg injection [1 vial] (& inert substance diluent [2 mL ampoule], 1 pack**

9379P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1050.60	38.80	Diphereline [IS]

**triptorelin 22.5 mg injection [1 vial] (& inert substance diluent [2 mL ampoule], 1 pack**

5297T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2021.67	38.80	Diphereline [IS]

**HORMONE ANTAGONISTS AND RELATED AGENTS***Anti-estrogens***TAMOXIFEN****Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 10 mg tablet, 60**

2109B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.05	21.26	Genox 10 [AF]

▪ **TAMOXIFEN**

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 30**

1880Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*26.61	27.82	<sup>a</sup> Nolvadex-D [AP]

▪ **TAMOXIFEN**

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 60**

2110C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.62	27.83	<sup>a</sup> Genox 20 [AF] <sup>a</sup> Tamosin [QA]	<sup>a</sup> GenRx Tamoxifen [GX] <sup>a</sup> Tamoxifen Sandoz [SZ]

▪ **TAMOXIFEN**

**Note** A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

**Note Continuing Therapy Only:**

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

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

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

**Restricted benefit**

Reduction of breast cancer risk

**Clinical criteria:**

- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

**tamoxifen 20 mg tablet, 30**

10911G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.85	20.06	<sup>a</sup> Genox 20 [AF]	<sup>a</sup> Nolvadex-D [AP]

▪ **TOREMIFENE**

**toremifene 60 mg tablet, 30**

8216K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	69.23	38.80	Fareston [AS]

Anti-androgens

▪ BICALUTAMIDE

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

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

5729

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**bicalutamide 50 mg tablet, 28**

8094B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	56.89	38.80	<sup>a</sup> APO-Bicalutamide [TX] <sup>a</sup> Bicalox [ER] <sup>a</sup> Calutex [QA] <sup>a</sup> Cosudex [AP]	<sup>a</sup> Bicalide [JU] <sup>a</sup> Bicalutamide AN [EA] <sup>a</sup> Cosamide 50 [AF]

▪ CYPROTERONE

**cyproterone acetate 100 mg tablet, 50**

8019C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	66.87	38.80	<sup>a</sup> ANTERONE 100 [RW] <sup>a</sup> Cyprone 100 [AF] <sup>a</sup> Cyproterone AN [EA] <sup>a</sup> GenRx Cyproterone Acetate [GX]	<sup>a</sup> Cyprocur 100 [QA] <sup>a</sup> Cyprostat-100 [SY] <sup>a</sup> Cyproterone Sandoz [HX] <sup>a</sup> Procur 100 [ED]
			<sup>b</sup> 1.41	68.28	38.80	<sup>a</sup> Androcur-100 [BN]	

**cyproterone acetate 50 mg tablet, 50**

1270W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*82.69	38.80	<sup>a</sup> ANTERONE 50 [RW] <sup>a</sup> Cyprone [AF] <sup>a</sup> Cyproterone AN [EA] <sup>a</sup> Cytotone [ER]	<sup>a</sup> Cyprocur 50 [QA] <sup>a</sup> Cyprostat [SY] <sup>a</sup> Cyproterone Sandoz [HX] <sup>a</sup> GenRx Cyproterone Acetate [GX]
			<sup>b</sup> 2.28	*84.97	38.80	<sup>a</sup> Androcur [BN]	

▪ ENZALUTAMIDE

**Note** Special Pricing Arrangements apply.

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

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

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must not have received prior treatment with abiraterone; OR
- Patient must have developed intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.

**enzalutamide 40 mg capsule, 112**

10174L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3702.82	38.80	Xtandi [LL]

▪ FLUTAMIDE

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

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6611**

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**flutamide 250 mg tablet, 30**

2742H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*154.30	38.80	Flutamide MYLAN [AF]

**FLUTAMIDE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5816**

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**flutamide 250 mg tablet, 100**

1417N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	170.37	38.80	Flutamin [AF]

**LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

10963B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	1123.38	38.80	Bi ELIGARD CP [TL]

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack**

10969H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	1268.94	38.80	Bi ELIGARD CP [TL]

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

10962Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	472.21	38.80	Bi ELIGARD CP [TL]

**NILUTAMIDE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5785**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**Authority required (STREAMLINED)****5647**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in conjunction with surgical orchidectomy.

**nilutamide 150 mg tablet, 30**

8131Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	213.38	38.80	Anandron [SW]

*Aromatase inhibitors*

■ **ANASTROZOLE**

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**anastrozole 1 mg tablet, 30**

8179L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	29.13	30.34	<sup>a</sup> Anastrozol [QA] <sup>a</sup> Anastrozole FBM [FO] <sup>a</sup> Anastrozole Sandoz [SZ] <sup>a</sup> Arianna 1 [AF] <sup>a</sup> Astzol [JU]	<sup>a</sup> Anastrozole AN [EA] <sup>a</sup> Anastrozole GH [GQ] <sup>a</sup> APO-Anastrozole [TX] <sup>a</sup> Arimidex [AP] <sup>a</sup> Azastrale [ER]

■ **EXEMESTANE**

**Restricted benefit**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**

- Patient must not be pre-menopausal.

**exemestane 25 mg tablet, 30**

10103R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	66.59	38.80	<sup>a</sup> APO-Exemestane [TX] <sup>a</sup> Exaccord [RA] <sup>a</sup> Exemestane GH [GQ]	<sup>a</sup> Estamane [JU] <sup>a</sup> Exemestane AN [EA] <sup>a</sup> Exemestane Sandoz [SZ]
			<sup>B</sup> 4.00	70.59	38.80	<sup>a</sup> Aromasin [PF]	

■ **EXEMESTANE**

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**exemestane 25 mg tablet, 30**

8506Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	66.59	38.80	<sup>a</sup> APO-Exemestane [TX] <sup>a</sup> Exaccord [RA] <sup>a</sup> Exemestane GH [GQ]	<sup>a</sup> Estamane [JU] <sup>a</sup> Exemestane AN [EA] <sup>a</sup> Exemestane Sandoz [SZ]
			<sup>B</sup> 4.00	70.59	38.80	<sup>a</sup> Aromasin [PF]	

■ **LETROZOLE**

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**letrozole 2.5 mg tablet, 30**

8245Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.88	32.09	<sup>a</sup> APO-Letrozole [TX] <sup>a</sup> Femara 2.5 mg [NV] <sup>a</sup> Fera [QA] <sup>a</sup> Letroz [JU] <sup>a</sup> Letrozole FBM [FO] <sup>a</sup> Letrozole RBX [RA] <sup>a</sup> Pharmacor Letrozole 2.5 [CR]	<sup>a</sup> Chem mart Letrozole [CH] <sup>a</sup> Femolet [AF] <sup>a</sup> Gynotril [ER] <sup>a</sup> Letrozole AN [EA] <sup>a</sup> Letrozole generichealth [GQ] <sup>a</sup> Letrozole Sandoz [SZ] <sup>a</sup> Terry White Chemists Letrozole [TW]

*Other hormone antagonists and related agents***ABIRATERONE**

**Note** Special Pricing Arrangements apply.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone, **AND**
- Patient must not have received prior treatment with enzalutamide; OR
- Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

**abiraterone acetate 500 mg tablet, 60**

11206T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3603.06	38.80	Zytiga [JC]

**abiraterone acetate 250 mg tablet, 120**

2698B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3603.06	38.80	Zytiga [JC]

**DEGARELIX****Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 80 mg injection [1 vial] (& inert substance diluent [1 syringe], 1 pack**

2784M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	393.95	38.80	Firmagon 80mg [FP]

**DEGARELIX**

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 120 mg injection [2 vials] (& inert substance diluent [2 syringes], 1 pack**

2785N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	412.15	38.80	Firmagon 120mg [FP]

**IMMUNOSTIMULANTS****IMMUNOSTIMULANTS***Interferons*

### ■ INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Myeloproliferative disease

**Clinical criteria:**

- Patient must have excessive thrombocytosis.

#### interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

8553E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	4	..	*477.25	38.80	Roferon-A [RO]

### ■ INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Low grade non-Hodgkin's lymphoma

**Clinical criteria:**

- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

#### interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

8181N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15	5	..	*477.40	38.80	Roferon-A [RO]

#### interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

8184R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*477.25	38.80	Roferon-A [RO]

### ■ INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Hairy cell leukaemia

**Authority required**

Myeloproliferative disease

**Clinical criteria:**

- Patient must have excessive thrombocytosis.

#### interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

8180M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15	4	..	*477.40	38.80	Roferon-A [RO]

### ■ INTERFERON ALFA-2B

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Hairy cell leukaemia

#### interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL

8572E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	4	..	*571.66	38.80	Intron A Redipen [MK]

### ■ INTERFERON ALFA-2B

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Multiple myeloma

Treatment Phase: Maintenance treatment

**Clinical criteria:**

- The condition must be in remission following chemotherapy.

**Authority required**

Low grade non-Hodgkin's lymphoma

**Clinical criteria:**

- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

8476D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*949.60	38.80	Intron A Redipen [MK]

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

8348J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*571.66	38.80	Intron A Redipen [MK]

**■ INTERFERON BETA-1A**

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

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

**Authority required (STREAMLINED)****4881**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)****6860**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12**

8968B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	998.56	38.80	Rebif 44 [SG]

**interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 mL syringes**

8805K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	998.56	38.80	Avonex [BD]

**interferon beta-1a 44 microgram/0.5 mL (12 million units) injection, 12 x 0.5 mL syringes**

8403G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	998.56	38.80	Rebif 44 [SG]

**interferon beta-1a 132 microgram/1.5 mL (12 million units) injection, 4 x 1.5 mL cartridges**

9332E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	998.56	38.80	Rebif 44 [SG]

**■ INTERFERON BETA-1B**

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

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

**Authority required (STREAMLINED)****4881**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**

- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

**6860**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack**

8101J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	994.39	38.80	Betaferon [BN]

▪ **PEGINTERFERON ALFA-2A**

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

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

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

11037X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	1404.79	38.80	Pegasys [RO]

▪ **PEGINTERFERON BETA-1A**

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

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

**Authority required (STREAMLINED)**

**4881**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices**

10212L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1050.09	38.80	Plegridy [BD]

**peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1 pack**

10218T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	1050.09	38.80	Plegridy [BD]

▪ **PEGINTERFERON BETA-1A**

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

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

**Authority required (STREAMLINED)****6860**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices**

10220X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1050.09	38.80	Plegridy [BD]

*Other immunostimulants***▪ BACILLUS CALMETTE AND GUERIN-TICE STRAIN****Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

**Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 vials**

1131M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	524.75	38.80	OncoTICE [MK]

**▪ GLATIRAMER ACETATE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****4881**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)****6860**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes**

10416F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1035.03	38.80	Copaxone [TB]

**glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes**

8726G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1035.03	38.80	Copaxone [TB]

**▪ IMMUNOSUPPRESSANTS****IMMUNOSUPPRESSANTS***Selective immunosuppressants***▪ ABATACEPT****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term

bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF- $\alpha$  antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
 Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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

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

**Authority required**

Severe active rheumatoid arthritis  
 Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

11068M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	953.23	38.80	Orencia ClickJect [BQ]

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

1221G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	953.23	38.80	Orencia [BQ]

▪ **ABATACEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Abatacept patients:** Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

**Rituximab patients:** A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. **Rituximab patients:** A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

**Abatacept:** Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

**Rituximab:** In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

- (1) completed authority prescription forms; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

(a) completed authority prescription forms; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application.

The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

11092T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	953.23	38.80	Orencia ClickJect [BQ]

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

1220F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	953.23	38.80	Orencia [BQ]

■ **EVEROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**everolimus 750 microgram tablet, 60**

8842J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1494.83	38.80	Certican [NV]

**everolimus 1 mg tablet, 60**

9352F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1967.37	38.80	Certican [NV]

**everolimus 500 microgram tablet, 60**

8841H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	512.87	38.80	Certican [NV]

**everolimus 250 microgram tablet, 60**

8840G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	258.84	38.80	Certican [NV]

**■ FINGOLIMOD**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

 **fingolimod 500 microgram capsule, 28**

5262Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2207.81	38.80	Gilenya [NV]

**■ LEFLUNOMIDE**

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Authority required (STREAMLINED)**

**5766**

Severe active psoriatic arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 20 mg tablet, 30**

5450W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	43.93	38.80	<sup>a</sup> Arabloc [AV] <sup>a</sup> Ataris 20 [AF] <sup>a</sup> Leflunomide Sandoz [SZ]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX]

**leflunomide 10 mg tablet, 30**

5449T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	32.65	33.86	<sup>a</sup> Arabloc [AV] <sup>a</sup> Ataris 10 [AF] <sup>a</sup> Leflunomide Sandoz [SZ]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX]

▪ **LEFLUNOMIDE**

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Authority required (STREAMLINED)**

**5681**

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 20 mg tablet, 30**

8375T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	43.93	38.80	<sup>a</sup> Arabloc [AV] <sup>a</sup> Ataris 20 [AF] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide AN [EA] <sup>a</sup> Leflunomide GH [GQ] <sup>a</sup> Lunava 20 [ZP]

**leflunomide 10 mg tablet, 30**

8374R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	32.65	33.86	<sup>a</sup> Arabloc [AV] <sup>a</sup> Ataris 10 [AF] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide AN [EA] <sup>a</sup> Leflunomide GH [GQ] <sup>a</sup> Lunava 10 [ZP]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**mycophenolate mofetil 500 mg tablet, 50**

8650G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	5	..	*152.89	38.80	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Ceptolate [AF] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> CellCept [RO] <sup>a</sup> Mycophenolate AN [EA] <sup>a</sup> Pharmacor Mycophenolate 500 [CR]

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

8651H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	#279.62	38.80	CellCept [RO]

**mycophenolate 360 mg enteric tablet, 120**

2193K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	195.71	38.80	Myfortic [NV]

**mycophenolate 180 mg enteric tablet, 120**

2150E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	103.33	38.80	Myfortic [NV]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

**mycophenolate mofetil 250 mg capsule, 100**

8649F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	5	..	*152.95	38.80	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> CellCept [RO] <sup>a</sup> Pharmacor Mycophenolate 250 [CR]

**mycophenolate Capsule 250 mg, 50**

8136P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*152.95	38.80	<sup>a</sup> Ceptolate [AF]

**■ SIROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**sirolimus 1 mg tablet, 100**

8724E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	769.48	38.80	Rapamune [PF]

**sirolimus 2 mg tablet, 100**

8833X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1499.62	38.80	Rapamune [PF]

**sirolimus 1 mg/mL oral liquid, 60 mL**

8725F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	499.55	38.80	Rapamune [PF]

**sirolimus 500 microgram tablet, 100**

8984W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	387.15	38.80	Rapamune [PF]

**■ TERIFLUNOMIDE**

**Caution** Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**teriflunomide 14 mg tablet, 28**

2898M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1837.26	38.80	Aubagio [GZ]

**■ TOFACITINIB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term

bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF- $\alpha$  antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

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#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:  
 (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
 (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
 Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tofacitinib 5 mg tablet, 56**

10511F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1267.40	38.80	Xeljanz [PF]

■ **TOFACITINIB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:  
 (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
 (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
 The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

- (a) a completed authority prescription form and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (Grandfather patients)

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 October 2015, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

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

- a completed authority prescription form; and
- a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- a signed patient acknowledgement.

All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **tofacitinib 5 mg tablet, 56**

10517M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1267.40	38.80	Xeljanz [PF]

### ***Tumor necrosis factor alpha (TNF-) inhibitors***

#### **■ ADALIMUMAB**

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment

applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Initial 3 (grandfathered patients) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 16 weeks of therapy (new patients or change/re-commencement patients; Initial 1 or Initial 2) or 24 weeks of therapy (Continuing patients or Grandfathered patients).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

10400J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1401.83	38.80	Humira [VE]

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

10399H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1401.83	38.80	Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

10422M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1401.83	38.80	Humira [VE]

▪ **ADALIMUMAB**

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

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment – balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 1 - New patient restriction to complete a maximum of 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 2 - Recommencement of treatment restriction to complete a maximum of 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

**adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges**

11133Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2709.24	38.80	Humira [VE]

## ■ ADALIMUMAB

### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of

the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

5284D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

5283C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

### ■ ADALIMUMAB

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au).

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia  
Prior Written Approval of Specialised Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

#### **Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note** No applications for increased maximum quantities and/or repeats will be authorised.

#### **Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and  
(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be

requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

#### **Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
- (c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

#### **adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes**

8961P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

8965W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1401.83	38.80	Humira [VE]

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

8963R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1401.83	38.80	Humira [VE]

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

8962Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

**■ ADALIMUMAB**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au).

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia  
Prior Written Approval of Specialised Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note** No applications for increased maximum quantities and/or repeats will be authorised.

#### **Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with adalimumab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

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

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

8966X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

8964T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

**ADALIMUMAB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 1 month old at the time of application.

An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply

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

- (a) a completed authority prescription form; and
- (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:
  - (i) the Hurley stage grading; and
  - (ii) the AN count; and
  - (iii) the name of the antibiotic/s received for two separate courses each of three months; or
  - (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics
  - (v) a signed patient acknowledgement.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 2 - Recommencement of treatment

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 1 month old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply

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

- (a) a completed authority prescription form; and
- (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:
  - (i) the Hurley stage grading; and
  - (ii) the AN count.

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

11132X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

▪ **ADALIMUMAB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

- a completed authority prescription form; and
- a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 3 - Grandfathered patient

**Clinical criteria:**

- Patient must have been receiving treatment with this drug for this condition prior to 1 July 2017, **AND**
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug, **AND**
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer, **AND**

- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Assessment of disease severity must be no more than 1 month old at the time treatment with this drug was initiated.

A maximum of 24 weeks treatment will be authorised under this restriction.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria or recommencement of treatment criteria where there is a break in treatment.

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

- a completed authority prescription form; and
- completed hidradenitis suppurativa PBS authority application supporting Information form which must include:
  - the Hurley stage grading; and
  - the AN count; and
  - the name of the antibiotic/s received for two separate courses each of three months; or
  - confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics
  - the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment

(vi) a signed patient acknowledgement.

### adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges

11137E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2709.24	38.80	Humira [VE]

#### ■ ADALIMUMAB

**Note** No applications for increased maximum quantities will be authorised.

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One

prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
- the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
- the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9191R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

9189P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

**■ ADALIMUMAB**

**Note** Special Pricing Arrangements apply.

**Note** No applications for increased maximum quantities will be authorised.

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF- $\alpha$  antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF- $\alpha$  antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF- $\alpha$  antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF- $\alpha$  antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF- $\alpha$  antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF- $\alpha$  antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF- $\alpha$  antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF- $\alpha$  antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF- $\alpha$  antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF- $\alpha$  antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF- $\alpha$  antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF- $\alpha$  antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF- $\alpha$  antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF- $\alpha$  antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- $\alpha$  antagonist.

For second and subsequent courses of PBS-subsidised TNF- $\alpha$  antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF- $\alpha$  antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF- $\alpha$  antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF- $\alpha$  antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- $\alpha$  antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF- $\alpha$  antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF- $\alpha$  antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF- $\alpha$  antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF- $\alpha$  antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF- $\alpha$  antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF- $\alpha$  antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted

within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF- $\alpha$  antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

#### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)).

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients

40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

- two completed authority prescription form; and
- a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:
  - the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
  - details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response

assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

10404N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

10413C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1401.83	38.80	Humira [VE]

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

10419J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1401.83	38.80	Humira [VE]

#### adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10389T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

#### adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges

10397F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

### ■ ADALIMUMAB

**Note** Special Pricing Arrangements apply.

**Note** No applications for increased maximum quantities will be authorised.

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF- $\alpha$  antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF- $\alpha$  antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF- $\alpha$  antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- $\alpha$  antagonist.

For second and subsequent courses of PBS-subsidised TNF- $\alpha$  antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF- $\alpha$  antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF- $\alpha$  antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF- $\alpha$  antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- $\alpha$  antagonist.

#### (2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF- $\alpha$  antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF- $\alpha$  antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF- $\alpha$  antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF- $\alpha$  antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF- $\alpha$  antagonist the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF- $\alpha$  antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

#### (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF- $\alpha$  antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

#### (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with this drug (Initial 3 - Grandfather)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have been receiving treatment with this drug prior to 1 August 2015, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have had disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on prior conventional treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation of initial treatment must be in writing and must include:

- a completed authority prescription form; and
- a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:
  - the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet;
  - the date of commencement of this drug; and
  - the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The patient's current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with this drug.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

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

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

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

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

10420K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

10412B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

#### adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10396E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

### ■ ADALIMUMAB

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which

are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**

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

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of

the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**

- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

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

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

5282B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

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

5281Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

**ADALIMUMAB****Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the

commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

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

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9104E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

9078T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

**ADALIMUMAB****Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
 (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
 Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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

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

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9100Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

8741C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

## **ADALIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a

biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-

trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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

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

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9102C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

9034L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

## ADALIMUMAB

### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

- (i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for

the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alpha antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alpha antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised TNF-alpha antagonist therapy after 1 June 2017. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alpha antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alpha antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alpha antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alpha antagonist. For second and subsequent courses of PBS-subsidised TNF-alpha antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats. (b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alpha antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alpha antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alpha antagonist supply. Assessments of response to a course of PBS-subsidised

treatment must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate agent at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured.(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Re-commencement of treatment after more than 5 years break in therapy - Initial 1)

#### **Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:(a) two completed authority prescription forms; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and(iii) the signed patient acknowledgement or guardian acknowledgement.

For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break of less than 5 years in therapy (Initial 2)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with adalimumab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with adalimumab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric

Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** No applications for increased repeats will be authorised.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial 1 and Initial 2

#### **Clinical criteria:**

- Patient must have received insufficient treatment with this drug under the Initial 1 (new patient or recommencement of treatment after more than 5 years break in therapy) restriction to complete 16 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug under the Initial 2 (Change or Re-commencing of treatment after less than 5 years break in therapy) to complete 16 weeks of treatment.

#### **Population criteria:**

- Patient must be 6 years of age or older.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services.

#### **adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes**

10972L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

10955N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1401.83	38.80	Humira [VE]

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

10944B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1401.83	38.80	Humira [VE]

#### **adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

11127P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

#### **adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

10945C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

### ■ ADALIMUMAB

#### **Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-

subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

- (i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate agent at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is

measured.(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

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

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 3 (Grandfathered patient)

**Clinical criteria:**

- Patient must have a documented history of moderate to severe ulcerative colitis, **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have a Mayo score greater than or equal to 6 prior to commencing treatment with this drug; OR
- Patient must have a partial Mayo score is greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug, if aged 6 to 17 years; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, if aged 6 to 17 years, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheets including the dates of assessment of the patient's condition; and (ii) the date of commencement of this drug; and (iii) the signed patient or guardian acknowledgement

The current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

**Note** No applications for increased repeats will be authorised.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Continuing treatment and Initial 3 (Grandfathered patients)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial 3 (Grandfathered patients).

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

10961X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

10960W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

11121H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

▪ **ADALIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF- $\alpha$  antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF- $\alpha$  antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose

when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF- $\alpha$  antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

- (a) a completed authority prescription form and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9099X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

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

8737W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

**ADALIMUMAB****Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

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

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

**AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

- a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; **AND**
- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

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

- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
  - a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
  - a completed BASDAI Assessment Form; and
  - a completed Exercise Program Self Certification Form included in the supporting information form; and
  - a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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

- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9103D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

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

9077R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

**ADALIMUMAB****Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMs) for adult patients with severe Crohn disease. Where the term bDMs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying

drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note** No applications for increased maximum quantities will be authorised.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the initial dose (i.e. the initial infusion regimen at weeks 0 and 2); OR

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 2 doses (new patients) or 5 repeats (Continuing treatment).

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 2 initial doses or 5 repeats may be requested by telephone by contacting the Department of Human Services

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

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes**

9186L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9190Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1401.83	38.80	Humira [VE]

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

9188N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1401.83	38.80	Humira [VE]

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

9187M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3989.10	38.80	Humira [VE]

**ADALIMUMAB****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

**(3) Swapping therapy.**

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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

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

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment

course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9101B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

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

9033K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1401.83	38.80	Humira [VE]

### **■ ADALIMUMAB**

#### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

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

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Resumption of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

- a completed authority prescription form; and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9428F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

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

9427E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1401.83	38.80	Humira [VE]

**ADALIMUMAB****Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

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

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a

patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

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

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to

determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
- (iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month

from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

- Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.
- Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or commencement of treatment after a break of less than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or commencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or commencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

- Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9426D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1401.83	38.80	Humira [VE]

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

9425C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1401.83	38.80	Humira [VE]

#### **■ CERTOLIZUMAB PEGOL**

- Note** Authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment should be forwarded to:  
Department of Human Services  
Prior Written Approval of Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10892G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1202.08	38.80	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

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

**Note** Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10897M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1202.08	38.80	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please

contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the

baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

3425G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1202.08	38.80	Cimzia [UC]

**■ CERTOLIZUMAB PEGOL****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**

- Patient must not have not failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times., **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

#### Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

- Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:
- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
  - (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
  - (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

- (a) a completed authority prescription form and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10905Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3549.97	38.80	Cimzia [UC]

**■ CERTOLIZUMAB PEGOL**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle'

(Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10896L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1202.08	38.80	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate

response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

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

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

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

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10137M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1202.08	38.80	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

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

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#### **Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

#### **Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

#### **AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; **AND**
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

- (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a completed BASDAI Assessment Form; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

#### **Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10904X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3549.97	38.80	Cimzia [UC]

### **■ CERTOLIZUMAB PEGOL**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle'

(Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
- For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10238W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1202.08	38.80	Cimzia [UC]

## ■ CERTOLIZUMAB PEGOL

### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10909E	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3549.97	38.80	Cimzia [UC]

### ■ ETANERCEPT

#### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**7217**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was issued in this cycle and the date of the first application under a new cycle.

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

11216H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Brenzys [MK]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

11202N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Brenzys [MK]

**■ ETANERCEPT****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient

has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

##### **7276**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

11211C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Brenzys [MK]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

11218K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Brenzys [MK]

▪ **ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be

used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**7168**

Active ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was issued in this cycle and the date of the first application under a new cycle.

#### **ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

11217J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Brenzys [MK]

#### **ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

11215G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Brenzys [MK]

### ▪ ETANERCEPT

#### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**7317**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**

- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required (STREAMLINED)**

**7296**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

11225T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Brenzys [MK]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

11221N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Brenzys [MK]

## ▪ ETANERCEPT

### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of

the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

3449M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

### ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

3450N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

3448L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

## ■ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the

prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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#### **Authority required**

Active ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Population criteria:**

- Patient must be 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Each application for continuing treatment with this drug must include a measurement of response to the prior course of therapy. If the response assessment is not submitted, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was issued in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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#### **Authority required**

Active ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

11196G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

### ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

11201M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11204Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

## ■ ETANERCEPT

### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing

they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Each application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. Where a response assessment is not submitted the patient will be deemed to have failed to respond to treatment with this drug.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5

years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

11208X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

11198J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11207W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

▪ **ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please

contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the

baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for subsequent continuing treatment with this product must include a measurement of response to the prior course of therapy.

Where a response assessment is not undertaken, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

11219L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

11220M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

**etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack**

11197H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

**■ ETANERCEPT****Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than

24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than

24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

3446J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

3447K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

3445H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.31	38.80	Enbrel [PF]

**■ ETANERCEPT****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing

they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:(1) a completed authority prescription form; and(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The application for first continuing treatment with this drug must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9090K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9460X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8638P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

▪ **ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for commencement after 5 years or more and initial 2 for commencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

The application for first continuing treatment following an initial treatment course must be made following a minimum of 12 weeks of treatment with this drug. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was issued in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9086F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

### **ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9456Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

### **etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8779C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

## **ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult

patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

#### (4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the

commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatments.

The application for first continuing treatment with this drug must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### **Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9088H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9458T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9036N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

**■ ETANERCEPT****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Each application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. Where a response assessment is not submitted the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Each application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. Where a response assessment is not submitted the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

11224R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

11222P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11223Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

**ETANERCEPT****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-

subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed

whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing or subsequent continuing treatment criteria, the patient must have been assessed for response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage ([www.health.gov.au/biosimilars](http://www.health.gov.au/biosimilars)).

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing or subsequent continuing treatment criteria, the patient must have been assessed for response.

Where a response assessment is not undertaken, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9089J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9459W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8637N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.31	38.80	Enbrel [PF]

▪ **ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-

subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage ([www.health.gov.au/biosimilars](http://www.health.gov.au/biosimilars)).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy with this biological agent), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was accessed under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted, where applicable to the Department of Human Services.

Where this is the initial course of treatment with a particular biological agent (change of treatment) the assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was issued in this cycle and the date of the first application under a new cycle.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:

- a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9087G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9457R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9035M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.31	38.80	Enbrel [PF]

▪ **ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been

treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

The application for first continuing treatment with this drug must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The application for first continuing treatment with this drug must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9431J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9462B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9429G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.31	38.80	Enbrel [PF]

▪ **ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept,

golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients or recommencement of treatment after a break of 5 years or more)

#### **Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment for this condition with a biological disease modifying anti-rheumatic drug (bDMARD) in this treatment cycle, **AND**

- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

**AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage ([www.health.gov.au/biosimilars](http://www.health.gov.au/biosimilars)).

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing or subsequent continuing treatment criteria, patients must have been assessed for response.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was issued in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment– Initial 1 (new patients or recommencement of treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) – balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or recommencement of treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9085E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9455P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8778B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.31	38.80	Enbrel [PF]

**■ ETANERCEPT**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

**TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

- (i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
- (ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

- (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
- (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR

- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

- (i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
- (ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

- (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
- (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note** In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Whole body)

#### TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body, **AND**
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, **AND**
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (Face, hand, foot)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

- (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient's condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment of Re-treatment (Face, hand, foot) - balance of first supply

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note** In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Face, hand, foot)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, **AND**
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include :

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area digrams including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

1963H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	Enbrel [PF]

### ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

1964J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	Enbrel [PF]

### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

1954W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.31	38.80	Enbrel [PF]

## ■ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been

treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage ([www.health.gov.au/biosimilars](http://www.health.gov.au/biosimilars)).

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage ([www.health.gov.au/biosimilars](http://www.health.gov.au/biosimilars)).

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment,

#### **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9091L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9461Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.30	38.80	<sup>a</sup> Brenzys [MK]	<sup>a</sup> Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9037P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.31	38.80	Enbrel [PF]

**■ GOLIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose

for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

If a patient fails to demonstrate a response to treatment with golimumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3428K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1357.17	38.80	Simponi [JC]

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3429L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1357.17	38.80	Simponi [JC]

**■ GOLIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists

(adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF- $\alpha$  antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF- $\alpha$  antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-

subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.  
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- a completed authority prescription form and
- a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

- a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3426H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1357.17	38.80	Simponi [JC]

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3427J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1357.17	38.80	Simponi [JC]

## ■ GOLIMUMAB

### **Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3436W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1357.17	38.80	Simponi [JC]

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3437X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1357.17	38.80	Simponi [JC]

## ■ GOLIMUMAB

### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

#### (4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of

the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3432P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1357.17	38.80	Simponi [JC]

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3433Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1357.17	38.80	Simponi [JC]

**■ GOLIMUMAB****Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

#### **Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

#### **AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; **AND**
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
  - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
  - (ii) a completed BASDAI Assessment Form; and
  - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
  - (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3434R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1357.17	38.80	Simponi [JC]

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3435T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1357.17	38.80	Simponi [JC]

**■ GOLIMUMAB****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

**(3) Swapping therapy.**

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment

course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3430M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1357.17	38.80	Simponi [JC]

### **golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3431N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1357.17	38.80	Simponi [JC]

### **Interleukin inhibitors**

#### **▪ DACLIZUMAB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Multiple sclerosis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

#### **Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Patients should undergo monthly liver function testing while being treated with this drug.

**Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

Patients should undergo monthly liver function testing while being treated with this drug.

**Authority required**

Multiple sclerosis

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years prior to initiation of this drug, **AND**
- Patient must have received treatment with this drug for this condition prior to 1 May 2017, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- The treatment must not exceed 24 weeks under this restriction.

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Patients should undergo monthly liver function testing while being treated with this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**daclizumab 150 mg/mL injection, 1 mL injection device**

11101G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2232.85	38.80	Zinbryta [BD]

▪ **IXEKIZUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or  
 or  
 (ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or  
 (iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or  
 (iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug, **AND**
- Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (whole body), **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must have had disease, prior to treatment with this drug, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, **AND**
- Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (face, hand, foot), **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body or Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment, Whole body or Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ixekizumab 80 mg/mL injection, 2 x 1 mL injection devices**

11033Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3409.52	38.80	Taltz [LY]

**IXEKIZUMAB****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the

Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

- (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
- (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
- (iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy,

will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or commencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or commencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or commencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ixekizumab 80 mg/mL injection, 2 x 1 mL injection devices**

11032P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	3409.52	38.80	Taltz [LY]

▪ **SECUKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10494H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1586.28	38.80	Cosentyx [NV]

▪ **SECUKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) – balance of supply

#### **Clinical criteria:**

- Patient must have active, or had a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the initial 1 or 2 restrictions.

#### **Population criteria:**

- Patient must be an adult.
- Treatment criteria:**
- Must be treated by a rheumatologist.

**secukinumab 150 mg/mL injection, 1 mL injection device**

10893H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	804.59	38.80	Cosentyx [NV]

**■ SECUKINUMAB****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

- patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

**(3) Swapping therapy.**

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- they have not received PBS-subsidised treatment with that particular biological agent previously; or
- they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the

PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencing treatment after a break of less than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencing treatment after a break of less than 5 years) restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10901R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1586.28	38.80	Cosentyx [NV]

#### **secukinumab 150 mg/mL injection, 1 mL injection device**

10898N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	804.59	38.80	Cosentyx [NV]

### **■ SECUKINUMAB**

#### **Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial treatment – initial 1 (new patients or patients recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**

- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

**AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

### secukinumab 150 mg/mL injection, 1 mL injection device

10890E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*3170.59	38.80	Cosentyx [NV]

## ■ SECUKINUMAB

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte

sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active psoriatic arthritis

Treatment Phase: Initial 3 - grandfather treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received non-PBS treatment with this drug for this condition prior to 1 October 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement; and
- (4) the date of commencement of this drug; and
- (5) results of the baseline patient assessment prior to commencing treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active psoriatic arthritis

Treatment Phase: Initial 3 (grandfather treatment) or Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 3 (grandfather patients) restriction to complete maximum of 24 weeks treatment, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10899P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1586.28	38.80	Cosentyx [NV]

**secukinumab 150 mg/mL injection, 1 mL injection device**

10895K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	804.59	38.80	Cosentyx [NV]

**■ SECUKINUMAB****Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be

reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years )

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received

previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10894J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*6191.63	38.80	Cosentyx [NV]

**secukinumab 150 mg/mL injection, 1 mL injection device**

10900Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*3170.59	38.80	Cosentyx [NV]

▪ **SECUKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle

(Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10425Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1586.28	38.80	Cosentyx [NV]

### **■ SECUKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept,

golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 3 (grandfather treatment)

#### **Clinical criteria:**

- Patient must have confirmed ankylosing spondylitis, defined radiographically (plain X-ray) of Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, with the diagnosis confirmed by a rheumatologist, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 October 2016, **AND**

- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The baseline BASDAI assessment must be from immediately prior to commencing treatment with this drug. The patient's current BASDAI assessment and ESR and/or CRP measurements must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form; and
- (c) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (d) a completed BASDAI Assessment Form; and
- (e) a signed patient acknowledgment form;
- (f) the date commencement of this drug;
- (g) results of the baseline BASDAI assessment prior to commencing treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

**Note** The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 3 or Continuing treatment – balance of supply

#### **Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the initial 3 treatment restriction to complete 24 weeks of treatment, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **secukinumab 150 mg/mL injection, 1 mL injection device**

10906B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	804.59	38.80	Cosentyx [NV]

### **■ SECUKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a

biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

- Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and

submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and  
 (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10910F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*6191.63	38.80	Cosentyx [NV]

**■ TOCILIZUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Abatacept patients:** Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

**Rituximab patients:** A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. **Rituximab patients:** A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

**Abatacept:** Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

**Rituximab:** In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10954M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	953.23	38.80	Actemra Subcutaneous Injection [RO]

**▪ TOCILIZUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF- $\alpha$  antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF- $\alpha$  antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose

when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis initial PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include: (a) completed authority prescription form(s); and (b) a completed Rheumatoid Arthritis continuing PBS Authority Application - Supporting Information Form. Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or commencement of treatment after break of less than 24 months) – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or commencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10951J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	953.23	38.80	Actemra Subcutaneous Injection [RO]

#### **■ USTEKINUMAB**

##### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

9305R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4346.86	38.80	Stelara [JC]

## **■ USTEKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

#### (4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-

trials treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 May 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be an adult.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Special Pricing Arrangements apply.

### **ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

10767Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4346.86	38.80	Stelara [JC]

## ■ USTEKINUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a

single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more), Initial 2 (change or recommencement of treatment) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.  
No increase in the maximum number of repeats may be authorised.  
Special Pricing Arrangements apply.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

10774C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4346.86	38.80	Stelara [JC]

**■ USTEKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of

treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or  
 (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

9304Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4346.86	38.80	Stelara [JC]

**■ USTEKINUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more

than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2017, **AND**
- Patient must be receiving treatment with ustekinumab at the time of application, **AND**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease Grandfathered PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** No applications for increased maximum quantities will be authorised.

**Note** Increase in the maximum number of repeats of up to two may be authorised in patients whose dosing frequency is every 8 weeks.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment or Grandfathered treatment

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Grandfathered treatment restriction to complete 24 weeks of treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authority to prescribe may be made by phone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

11178H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*8614.15	38.80	Stelara [JC]

*Calcineurin inhibitors*

▪ **CYCLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**cyclosporin 100 mg/mL oral liquid, 50 mL**

8661W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*707.63	38.80	Neoral [NV]

**cyclosporin 25 mg capsule, 30**

8658Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*80.37	38.80	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 25 [NV]

**cyclosporin 10 mg capsule, 60**

8657P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*91.09	38.80	Neoral 10 [NV]

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## cyclosporin 50 mg capsule, 30

8659R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*155.25	38.80	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 50 [NV]

## cyclosporin 100 mg capsule, 30

8660T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*308.81	38.80	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 100 [NV]

## ■ TACROLIMUS

**Caution** Careful monitoring of patients is mandatory.

### tacrolimus 1 mg modified release capsule, 60

5300Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	152.63	38.80	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

### tacrolimus 2 mg capsule, 100

10871E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	561.21	38.80	Tacrolimus Sandoz [SZ]	

### tacrolimus 5 mg modified release capsule, 30

5451X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	422.35	38.80	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

### tacrolimus 500 microgram modified release capsule, 30

5299X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	51.43	38.80	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

### tacrolimus 500 microgram capsule, 100

8646C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	129.04	38.80	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 0.5 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

### tacrolimus 5 mg capsule, 50

8648E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	614.87	38.80	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 5 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

### tacrolimus 750 microgram capsule, 100

10870D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	213.45	38.80	Tacrolimus Sandoz [SZ]	

### tacrolimus 1 mg capsule, 100

8647D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	248.95	38.80	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 1 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

## Other immunosuppressants

## ■ AZATHIOPRINE


**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### azathioprine 25 mg tablet, 100

2688L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	23.25	24.46	<sup>a</sup> APO-Azathioprine [TX] <sup>a</sup> Azathioprine Sandoz [SZ]	<sup>a</sup> Azathioprine GH [GQ] <sup>a</sup> Imuran [AS]

### azathioprine 50 mg tablet, 100

2687K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	31.80	33.01	<sup>a</sup> APO-Azathioprine [TX] <sup>a</sup> Azathioprine AN [EA] <sup>a</sup> Azathioprine Sandoz [SZ]	<sup>a</sup> Azapin [RW] <sup>a</sup> Azathioprine GH [GQ] <sup>a</sup> Imazan [ER]

<sup>a</sup> Imuran [AS]

<sup>a</sup> Thioprine 50 [AF]

▪ **METHOTREXATE**

**methotrexate 10 mg tablet, 15**

2272N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	23.19	24.40	Methoblastin [PF]

**methotrexate 2.5 mg tablet, 30**

1622J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	16.92	18.13	Methoblastin [PF]

▪ **METHOTREXATE**

**Restricted benefit**

Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

1623K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	51.41	38.80	Methoblastin [PF]

▪ **PIRFENIDONE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must have not have an acute respiratory infection at the time of FVC testing.

Applications for authorisation of initial treatment must be in writing and must include:

- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis  
Treatment Phase: Initial treatment 3 - Grandfathering treatment

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2017, **AND**
- The condition must have been diagnosed through a multidisciplinary team, **AND**
- Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must have not have an acute respiratory infection at the time of FVC testing.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria or change or recommencement of treatment criteria.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Applications for authorisation of initial treatment must be in writing and must include:

- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**pirfenidone 267 mg capsule, 270**

11136D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3064.52	38.80	Esbriet [RO]

- **MUSCULO-SKELETAL SYSTEM**
- **ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS**
- ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS**
- Acetic acid derivatives and related substances*

▪ **DICLOFENAC**

**diclofenac sodium 100 mg suppository, 20**

1302M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	2	3	..	*27.51	28.72	Voltaren 100 [NV]

**diclofenac sodium 100 mg suppository, 20**

5079H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	2	..	..	*27.51	28.72	Voltaren 100 [NV]

▪ **DICLOFENAC**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**diclofenac sodium 50 mg enteric tablet, 50**

1300K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	3	..	13.14	14.35	<sup>a</sup> APO-Diclofenac [TX] <sup>a</sup> Diclofenac Amneal [ED] <sup>a</sup> Diclofenac Sandoz [SZ]	<sup>a</sup> Clonac 50 [RW] <sup>a</sup> Diclofenac AN [EA] <sup>a</sup> Fenac [AF]
			<sup>b</sup> 3.46	16.60	14.35	<sup>a</sup> Voltaren 50 [NV]	

**diclofenac sodium 25 mg enteric tablet, 50**

1299J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*14.03	15.24	<sup>a</sup> APO-Diclofenac [TX] <sup>a</sup> Diclofenac Amneal [ED] <sup>a</sup> Diclofenac Sandoz [SZ]	<sup>a</sup> Clonac 25 [RW] <sup>a</sup> Diclofenac AN [EA] <sup>a</sup> Fenac 25 [AF]
			<sup>b</sup> 3.44	*17.47	15.24	<sup>a</sup> Voltaren 25 [NV]	

▪ **DICLOFENAC**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**diclofenac sodium 50 mg enteric tablet, 50**

5077F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	13.14	14.35	<sup>a</sup> APO-Diclofenac [TX] <sup>a</sup> Diclofenac Amneal [ED] <sup>a</sup> Diclofenac Sandoz [SZ]	<sup>a</sup> Clonac 50 [RW] <sup>a</sup> Diclofenac AN [EA] <sup>a</sup> Fenac [AF]
			<sup>b</sup> 3.46	16.60	14.35	<sup>a</sup> Voltaren 50 [NV]	

**diclofenac sodium 25 mg enteric tablet, 50**

5076E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	2	..	..	*14.03	15.24	<sup>a</sup> APO-Diclofenac [TX] <sup>a</sup> Diclofenac Amneal [ED] <sup>a</sup> Diclofenac Sandoz [SZ]	<sup>a</sup> Clonac 25 [RW] <sup>a</sup> Diclofenac AN [EA] <sup>a</sup> Fenac 25 [AF]
			<sup>b</sup> 3.44	*17.47	15.24	<sup>a</sup> Voltaren 25 [NV]	

▪ **INDOMETHACIN**

**indomethacin 100 mg suppository, 20**

2757D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*25.07	26.28	Indocid [AS]

**indomethacin 100 mg suppository, 20**

5128X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	2	..	..	*25.07	26.28	Indocid [AS]

■ **INDOMETHACIN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indomethacin 25 mg capsule, 50**

2454E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*16.69	17.90	<sup>a</sup> Arthrexin [AF]
			<sup>B</sup> 4.04	*20.73	17.90	<sup>a</sup> Indocid [AS]

■ **INDOMETHACIN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indomethacin 25 mg capsule, 50**

5126T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*16.69	17.90	<sup>a</sup> Arthrexin [AF]
			<sup>B</sup> 4.04	*20.73	17.90	<sup>a</sup> Indocid [AS]

*Oxicams*

■ **MELOXICAM**

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

**Note** Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- Patient must be symptomatic.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- Patient must be symptomatic.

**meloxicam 15 mg tablet, 30**

8562P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.18	16.39	<sup>a</sup> APO-Meloxicam [TX]	<sup>a</sup> Chem mart Meloxicam 15 mg [CH]
						<sup>a</sup> Meloxiauro 15 [DO]	<sup>a</sup> Meloxibell [GQ]
						<sup>a</sup> Meloxicam AN [EA]	<sup>a</sup> Meloxicam-GA [ED]
						<sup>a</sup> Meloxicam Ranbaxy [RA]	<sup>a</sup> Meloxicam Sandoz [SZ]
						<sup>a</sup> Movalis 15 [RW]	<sup>a</sup> Moxicam 15 [AF]
						<sup>a</sup> Pharmacor Meloxicam 15 [CR]	<sup>a</sup> Terry White Chemists Meloxicam 15 mg [TW]
						<sup>B</sup> 2.50	17.68

**meloxicam 7.5 mg capsule, 30**

8887R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	13.89	15.10	<sup>a</sup> APO-Meloxicam [TX]	<sup>a</sup> Chem mart Meloxicam [CH]
						<sup>a</sup> Meloxicam Sandoz [SZ]	<sup>a</sup> Movalis 7.5 [RW]
						<sup>a</sup> Moxicam [AF]	<sup>a</sup> Terry White Chemists Meloxicam [TW]
						<sup>B</sup> 2.50	16.39

**meloxicam 7.5 mg tablet, 30**

8561N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	13.89	15.10	<sup>a</sup> APO-Meloxicam [TX]	<sup>a</sup> Chem mart Meloxicam 7.5 mg [CH]
						<sup>a</sup> Meloxiauro 7.5 [DO]	<sup>a</sup> Meloxibell [GQ]
						<sup>a</sup> Meloxicam AN [EA]	<sup>a</sup> Meloxicam-GA [ED]
						<sup>a</sup> Meloxicam Ranbaxy [RA]	<sup>a</sup> Meloxicam Sandoz [SZ]
						<sup>a</sup> Movalis 7.5 [RW]	<sup>a</sup> Moxicam 7.5 [AF]
						<sup>a</sup> Pharmacor Meloxicam 7.5 [CR]	<sup>a</sup> Terry White Chemists Meloxicam 7.5 mg [TW]
			<sup>B</sup> 2.50	16.39	15.10	<sup>a</sup> Mobic [BY]	

**meloxicam 15 mg capsule, 30**

8888T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.18	16.39	<sup>a</sup> APO-Meloxicam [TX]	<sup>a</sup> Chem mart Meloxicam [CH]
						<sup>a</sup> Meloxicam Sandoz [SZ]	<sup>a</sup> Movalis 15 [RW]
						<sup>a</sup> Moxicam [AF]	<sup>a</sup> Terry White Chemists Meloxicam [TW]
			<sup>B</sup> 2.50	17.68	16.39	<sup>a</sup> Mobic [BY]	

**PIROXICAM**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**piroxicam 20 mg dispersible tablet, 25**

1896T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.87	17.08	<sup>a</sup> Mobilis D-20 [AF]	
			<sup>B</sup> 8.00	23.87	17.08	<sup>a</sup> Feldene-D [PF]	

**piroxicam 20 mg dispersible tablet, 25**

5202T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	15.87	17.08	<sup>a</sup> Mobilis D-20 [AF]	
			<sup>B</sup> 8.00	23.87	17.08	<sup>a</sup> Feldene-D [PF]	

**piroxicam 20 mg capsule, 25**

1898X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.87	17.08	<sup>a</sup> GenRx Piroxicam [GX]	<sup>a</sup> Mobilis 20 [AF]
			<sup>B</sup> 8.00	23.87	17.08	<sup>a</sup> Feldene [PF]	

**piroxicam 20 mg capsule, 25**

5204X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	15.87	17.08	<sup>a</sup> GenRx Piroxicam [GX]	<sup>a</sup> Mobilis 20 [AF]
			<sup>B</sup> 8.00	23.87	17.08	<sup>a</sup> Feldene [PF]	

**piroxicam 10 mg dispersible tablet, 50**

1895R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.12	17.33	Mobilis D-10 [AF]	

**piroxicam 10 mg dispersible tablet, 50**

5201R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.12	17.33	Mobilis D-10 [AF]	

**piroxicam 10 mg capsule, 50**

1897W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.12	17.33	<sup>a</sup> GenRx Piroxicam [GX]	<sup>a</sup> Mobilis 10 [AF]
			<sup>B</sup> 8.00	24.12	17.33	<sup>a</sup> Feldene [PF]	

**piroxicam 10 mg capsule, 50**

5203W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.12	17.33	<sup>a</sup> GenRx Piroxicam [GX]	<sup>a</sup> Mobilis 10 [AF]
			<sup>B</sup> 8.00	24.12	17.33	<sup>a</sup> Feldene [PF]	

*Propionic acid derivatives*

■ **IBUPROFEN**

**ibuprofen 400 mg tablet, 30**

3192B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	13.01	14.22	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> Brufen [GO]

**ibuprofen 400 mg tablet, 30**

5124Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	13.01	14.22	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> Brufen [GO]

■ **IBUPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

3190X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	3	3	..	*16.84	18.05	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> Brufen [GO]

■ **IBUPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

5123P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	3	..	..	*16.84	18.05	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> Brufen [GO]

■ **KETOPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**ketoprofen 200 mg modified release capsule, 28**

1590Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	3	..	22.12	23.33	<sup>a</sup> Oruvail SR [AV]
			<sup>B</sup> 1.92	24.04	23.33	<sup>a</sup> Orudis SR 200 [SW]

**ketoprofen 200 mg modified release capsule, 28**

5136H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	22.12	23.33	<sup>a</sup> Oruvail SR [AV]
			<sup>B</sup> 1.92	24.04	23.33	<sup>a</sup> Orudis SR 200 [SW]

■ **NAPROXEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 1 g modified release tablet, 28**

1615B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	3	..	17.65	18.86	<sup>a</sup> Proxen SR 1000 [IY]

			<sup>B</sup> 1.12	18.77	18.86	<sup>a</sup> Naprosyn SR1000 [IX]
<b>naproxen 250 mg tablet, 50</b>						
1674D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*18.35	19.56	<sup>a</sup> Inza 250 [AF]
			<sup>B</sup> 2.24	*20.59	19.56	<sup>a</sup> Naprosyn [IX]

<b>naproxen 500 mg tablet, 50</b>						
1659H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.46	17.67	<sup>a</sup> Inza 500 [AF]
			<sup>B</sup> 1.12	17.58	17.67	<sup>a</sup> Naprosyn [IX]

<b>naproxen 750 mg modified release tablet, 28</b>						
1614Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.01	17.22	<sup>a</sup> Proxen SR 750 [IY]
			<sup>B</sup> 1.06	17.07	17.22	<sup>a</sup> Naprosyn SR750 [IX]

▪ **NAPROXEN**

**Authority required (STREAMLINED)**

**4159**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**Authority required (STREAMLINED)**

**4124**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**naproxen 125 mg/5 mL oral liquid, 474 mL**

1658G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	121.27	38.80	Phebra Naproxen Suspension [PL]

▪ **NAPROXEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 1 g modified release tablet, 28**

5179N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	17.65	18.86	<sup>a</sup> Proxen SR 1000 [IY]
			<sup>B</sup> 1.12	18.77	18.86	<sup>a</sup> Naprosyn SR1000 [IX]

**naproxen 250 mg tablet, 50**

5176K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*18.35	19.56	<sup>a</sup> Inza 250 [AF]
			<sup>B</sup> 2.24	*20.59	19.56	<sup>a</sup> Naprosyn [IX]

**naproxen 500 mg tablet, 50**

5177L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.46	17.67	<sup>a</sup> Inza 500 [AF]
			<sup>B</sup> 1.12	17.58	17.67	<sup>a</sup> Naprosyn [IX]

**naproxen 750 mg modified release tablet, 28**

5178M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.01	17.22	<sup>a</sup> Proxen SR 750 [IY]
			<sup>B</sup> 1.06	17.07	17.22	<sup>a</sup> Naprosyn SR750 [IX]

▪ **NAPROXEN**

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen sodium 550 mg tablet, 50**

1795L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.61	17.82	<sup>a</sup> Crysanal [IY]
			<sup>b</sup> 1.89	18.50	17.82	<sup>a</sup> Anaprox 550 [IX]

▪ **NAPROXEN**

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen sodium 550 mg tablet, 50**

5186Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.61	17.82	<sup>a</sup> Crysanal [IY]
			<sup>b</sup> 1.89	18.50	17.82	<sup>a</sup> Anaprox 550 [IX]

*Fenamates*

▪ **MEFENAMIC ACID**

**Restricted benefit**

Dysmenorrhoea

**Restricted benefit**

Menorrhagia

**mefenamic acid 250 mg capsule, 50**

1824B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	20.80	22.01	Ponstan [PF]

*Coxibs*

▪ **CELECOXIB**

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**celecoxib 100 mg capsule, 60**

8439E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	18.03	19.24	<sup>a</sup> APO-Celecoxib [TX]	<sup>a</sup> Blooms the Chemist Celecoxib [IB]
						<sup>a</sup> Celaxib [AF]	<sup>a</sup> Celebrex [PF]
						<sup>a</sup> Celecoxib AN [EA]	<sup>a</sup> Celecoxib GH [GQ]
						<sup>a</sup> Celecoxib RBX [RA]	<sup>a</sup> Celecoxib Sandoz [SZ]
						<sup>a</sup> Celexi [RW]	<sup>a</sup> Chem mart Celecoxib [CH]
						<sup>a</sup> Terry White Chemists Celecoxib [TW]	

**celecoxib 200 mg capsule, 30**

8440F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	18.03	19.24	<sup>a</sup> APO-Celecoxib [TX]	<sup>a</sup> Blooms the Chemist Celecoxib [IB]
						<sup>a</sup> Celaxib [AF]	<sup>a</sup> Celebrex [PF]
						<sup>a</sup> Celecoxib AN [EA]	<sup>a</sup> Celecoxib GH [GQ]
						<sup>a</sup> Celecoxib RBX [RA]	<sup>a</sup> Celecoxib Sandoz [SZ]
						<sup>a</sup> Celexi [RW]	<sup>a</sup> Chem mart Celecoxib [CH]
						<sup>a</sup> Terry White Chemists Celecoxib [TW]	

**SPECIFIC ANTIRHEUMATIC AGENTS***Quinolines***■ HYDROXYCHLOROQUINE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**hydroxychloroquine sulfate 200 mg tablet, 100**

1512N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	25.15	26.36	<sup>a</sup> APO- Hydroxychloroquine [TX]	<sup>a</sup> Chem mart Hydroxychloroquine [CH]
						<sup>a</sup> Hequinel [RW]	<sup>a</sup> Hydroxychloroquine AN [EA]
						<sup>a</sup> Hydroxychloroquine GH [GQ]	<sup>a</sup> Hydroxychloroquine RBX [RA]
						<sup>a</sup> Plaquenil [SW]	<sup>a</sup> Terry White Chemists Hydroxychloroquine [TW]

*Gold preparations***■ AURANOFIN**

**Caution** Regular blood and urine checks are essential.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**auranofin 3 mg capsule, 60**

2022K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	773.65	38.80	Ridaura [BZ]

**auranofin 3 mg tablet, 60**

1095P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	238.01	38.80	Ridaura [GH]

**■ SODIUM AUROTHIOMALATE**

**Caution** Regular blood and urine checks are essential.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**sodium aurothiomalate 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

2016D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	77.48	38.80	Myocrisin [SW]

**sodium aurothiomalate 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

2017E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	113.23	38.80	Myocrisin [SW]

**sodium aurothiomalate 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

2018F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	137.22	38.80	Myocrisin [SW]

*Penicillamine and similar agents***■ PENICILLAMINE**

**Caution** Regular blood and urine checks are essential.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**penicillamine 250 mg tablet, 100**

2838J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	51.35	38.80	D-Penaminate [AL]

**penicillamine 125 mg tablet, 100**

2721F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	45.17	38.80	D-Penaminate [AL]

**MUSCLE RELAXANTS**

**MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS**

*Other centrally acting agents*

**BACLOFEN**

**baclofen 10 mg tablet, 100**

2729P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.07	22.28	<sup>a</sup> APO-Baclofen [TX] <sup>a</sup> GenRx Baclofen [GX] <sup>a</sup> Stelax 10 [RW]	<sup>a</sup> Clofen 10 [AF] <sup>a</sup> Lioresal 10 [NV]

**baclofen 25 mg tablet, 100**

2730Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	32.90	34.11	<sup>a</sup> APO-Baclofen [TX] <sup>a</sup> GenRx Baclofen [GX] <sup>a</sup> Stelax 25 [RW]	<sup>a</sup> Clofen 25 [AF] <sup>a</sup> Lioresal 25 [NV]

**MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS**

*Dantrolene and derivatives*

**DANTROLENE**

**Restricted benefit**

Chronic spasticity

**dantrolene sodium 25 mg capsule, 100**

1779P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	75.67	38.80	Dantrium [PF]

**dantrolene sodium 50 mg capsule, 100**

1780Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	76.20	38.80	Dantrium [PF]

**ANTIGOUT PREPARATIONS**

**ANTIGOUT PREPARATIONS**

*Preparations inhibiting uric acid production*

**ALLOPURINOL**

**Note** The dose should be adjusted in accordance with renal function.

**allopurinol 300 mg tablet, 60**

2604C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	14.61	15.82	<sup>a</sup> Allopurinol APOTEX [GX] <sup>a</sup> Allosig [RF] <sup>a</sup> Chem mart Allopurinol [CH] <sup>a</sup> Terry White Chemists Allopurinol [TW]	<sup>a</sup> Allopurinol Sandoz [SZ] <sup>a</sup> APO-Allopurinol [TX] <sup>a</sup> Pro gout 300 [AF]
			<sup>b</sup> 3.48	18.09	15.82	<sup>a</sup> Zyloprim [RW]	

**ALLOPURINOL**

**Note** The dose should be adjusted in accordance with renal function.

**Note** For item codes 2600W and 1557Y, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

**allopurinol 100 mg tablet, 100**

1557Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*15.95	17.16	<sup>a</sup> Pro gout 100 [AF]

**allopurinol 100 mg tablet, 200**

2600W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.95	17.16	<sup>a</sup> Allopurinol APOTEX [GX] <sup>a</sup> Allosig [RF] <sup>a</sup> Chem mart Allopurinol [CH] <sup>a</sup> Terry White Chemists Allopurinol [TW]	<sup>a</sup> Allopurinol Sandoz [SZ] <sup>a</sup> APO-Allopurinol [TX] <sup>a</sup> Pro gout 100 [AF]
			<sup>b</sup> 3.47	19.42	17.16	<sup>a</sup> Zyloprim [RW]	

**■ FEBUXOSTAT****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Chronic gout

**Clinical criteria:**

- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

**febuxostat 80 mg tablet, 28**

10445R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	50.94	38.80	Adenuric [FK]

*Preparations increasing uric acid excretion***■ PROBENECID****probenecid 500 mg tablet, 100**

1940D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	70.91	38.80	Pro-Cid [PL]

*Preparations with no effect on uric acid metabolism***■ COLCHICINE****colchicine 500 microgram tablet, 30**

3410L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.07	16.28	<sup>a</sup> Lengout [LN]
			<sup>b</sup> 2.90	17.97	16.28	<sup>a</sup> Colgout [AS]

**■ DRUGS FOR TREATMENT OF BONE DISEASES****DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION***Bisphosphonates***■ ALENDRONATE****Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**alendronate 70 mg tablet, 4**

8511Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.00	16.21	<sup>a</sup> Alendrobell 70mg [GQ] <sup>a</sup> Alendronate Sandoz [SZ] <sup>a</sup> APO-Alendronate [TX] <sup>a</sup> Fonat [AL]	<sup>a</sup> Alendronate AN [EA] <sup>a</sup> Alendro Once Weekly [RW] <sup>a</sup> Densate 70 [DO]

▪ **CLODRONATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**Restricted benefit**

Multiple myeloma

**Restricted benefit**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**clodronate sodium 800 mg tablet, 60**

8265B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	365.66	38.80	Bonefos 800 mg [BN]

**clodronate sodium 400 mg capsule, 100**

8132B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	309.26	38.80	Bonefos [BN]

▪ **IBANDRONATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**ibandronate 50 mg tablet, 28**

9357L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	317.38	38.80	Bondronat [RO]

▪ **PAMIDRONATE DISODIUM**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Symptomatic Paget disease of bone

**pamidronate disodium 60 mg/10 mL injection, 10 mL vial**

8463K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	70.51	38.80	Pamisol [PF]

**pamidronate disodium 15 mg/5 mL injection, 5 mL vial**

8461H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	..	..	*70.51	38.80	Pamisol [PF]

**pamidronate disodium 30 mg/10 mL injection, 10 mL vial**

8462J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*70.51	38.80	Pamisol [PF]

▪ **RISEDRONATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Symptomatic Paget disease of bone

**risedronate sodium 30 mg tablet, 28**

8482K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	175.09	38.80	Actonel [UA]

▪ **RISEDRONATE**

**Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**risedronate sodium 35 mg tablet, 4**

8621R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.10	36.31	<sup>a</sup> Acris Once-a-Week [AF] <sup>a</sup> Risedronate AN [EA] <sup>a</sup> Risedro once a week [RW]	<sup>a</sup> APO-Risedronate [TX] <sup>a</sup> Risedronate Sandoz [SZ]

**RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4**

8972F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	35.10	36.31	Actonel EC [UA]

**risedronate sodium 5 mg tablet, 28**

8481J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	35.10	36.31	Actonel [UA]

**risedronate sodium 150 mg tablet, 1**

9391G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.12	38.33	<sup>a</sup> Acris Once-a-Month [AF] <sup>a</sup> APO-Risedronate [TX]	<sup>a</sup> Actonel Once-a-Month [UA] <sup>a</sup> ATELVIA ONCE-A-MONTH [GN]

▪ **ZOLEDRONIC ACID**

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**5710**

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

9350D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	370.31	38.80	<sup>a</sup> Aclasta [HX] <sup>a</sup> Zoledasta [TX]	<sup>a</sup> Osteovan [SZ]

**zoledronic acid 5 mg/100 mL injection, 100 mL bag**

10571J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	370.31	38.80	<sup>a</sup> Ostira [PF]

▪ **ZOLEDRONIC ACID**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**6308**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.  
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6313**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.  
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6318**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**

- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

9288W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	370.31	38.80	<sup>a</sup> Aclasta [HX] <sup>a</sup> Zoledasta [TX]	<sup>a</sup> Osteovan [SZ]

**zoledronic acid 5 mg/100 mL injection, 100 mL bag**

10555M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	370.31	38.80	<sup>a</sup> Ostira [PF]

**Bisphosphonates, combinations****■ ALENDRONATE + COLECALCIFEROL**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)****6306**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
  - Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
  - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
- The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6325**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
  - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
- The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6319**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
  - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
- The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
- A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 140 microgram tablet, 4**

9183H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.94	19.15	<sup>a</sup> Alendronate plus D3-DRLA [RZ] <sup>a</sup> APO-Alendronate Plus D3 70 mg/140 mcg [TX] <sup>a</sup> Dronalen Plus [AL] <sup>a</sup> Terry White Chemists Alendronate Plus D3 70 mg/140 mcg [TW]	<sup>a</sup> Alendronate Plus D3 Sandoz [SZ] <sup>a</sup> Chem mart Alendronate Plus D3 70 mg/140 mcg [CH] <sup>a</sup> FonatPlus [AF]

<sup>B</sup>2.26      20.20      19.15      <sup>a</sup> Fosamax Plus 70 mg/140 mcg [MK]

■ **ALENDRONATE + COLECALCIFEROL**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

**Authority required (STREAMLINED)**

**6307**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6320**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6315**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 70 microgram tablet, 4**

9012H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.94	19.15	<sup>a</sup> Alendronate plus D3-DRLA [RZ] <sup>a</sup> APO-Alendronate Plus D3 70 mg/70 mcg [TX] <sup>a</sup> FonatPlus [AF]	<sup>a</sup> Alendronate Plus D3 Sandoz [SZ] <sup>a</sup> Chem mart Alendronate Plus D3 70 mg/70 mcg [CH] <sup>a</sup> Terry White Chemists Alendronate Plus D3 70 mg/70 mcg [TW]
				<sup>B</sup> 2.26	20.20	19.15	<sup>a</sup> Fosamax Plus [MK]

■ **ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

**6306**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6325**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6319**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack**

9351E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	22.83	24.04	<sup>a</sup> Dronalen Plus D-Cal [AF]	<sup>a</sup> ReddyMax Plus D-Cal [RZ]
			<sup>b</sup> 1.88	24.71	24.04	<sup>a</sup> Fosamax Plus D-Cal [MK]	

**■ RISEDRONATE (&) CALCIUM CARBONATE**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)****6306**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6325**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6319**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1**

8973G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	35.10	36.31	Actonel EC Combi [UA]

**risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28**

8899J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	35.10	36.31	Acris Combi [AF]

▪ **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

**6306**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6325**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6319**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1**

8974H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	35.10	36.31	Actonel EC Combi D [UA]

*Other drugs affecting bone structure and mineralization*

▪ **CALCITRIOL**

**Authority required (STREAMLINED)**

**5401**

Hypocalcaemia

**Clinical criteria:**

- The condition must be due to renal disease.

**Authority required (STREAMLINED)**

**5255**

Hypoparathyroidism

**Authority required (STREAMLINED)**

**5089**

Hypophosphataemic rickets

**Authority required (STREAMLINED)**

**5114**

Vitamin D-resistant rickets

**Authority required (STREAMLINED)**

**5402**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

2502Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	3	..	27.21	28.42	<sup>a</sup> APO-Calcitriol [TX] <sup>a</sup> Calcitriol AN [EA] <sup>a</sup> Sical [AF]	<sup>a</sup> Calciprox [ER] <sup>a</sup> Kosteo [RW]
			<sup>b</sup> 2.29	29.50	28.42	<sup>a</sup> Rocaltrol [RO]	

**■ DENOSUMAB**

**Note** Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4504**

Giant cell tumour of bone

**Clinical criteria:**

- Patient must be one in whom surgical resection is not feasible; OR
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

**Population criteria:**

- Patient must be an adult; OR
- Patient must be a skeletally mature adolescent.

**denosumab 120 mg/1.7 mL injection, 1.7 mL vial**

10061M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	501.67	38.80	Xgeva [AN]

**■ DENOSUMAB****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4158**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Authority required (STREAMLINED)****4150**

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.

**denosumab 120 mg/1.7 mL injection, 1.7 mL vial**

5110Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	501.67	38.80	Xgeva [AN]

**■ DENOSUMAB**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)****6548**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6524**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**denosumab 60 mg/mL injection, 1 mL syringe**

5457F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	271.49	38.80	Prolia [AN]

▪ **RALOXIFENE**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

**6314**

Established post-menopausal osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**raloxifene hydrochloride 60 mg tablet, 28**

8363E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	44.85	38.80	<sup>a</sup> APO-Raloxifene [TX] <sup>a</sup> Evista [LY] <sup>a</sup> Raloxifene AMNEAL [ED]	<sup>a</sup> Evifyne [EL] <sup>a</sup> Fixta 60 [DO] <sup>a</sup> Raloxifene AN [EA]

▪ **TERIPARATIDE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised agent, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au).

**Authority required**

Severe established osteoporosis  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 20 microgram injection, 2.4 mL cartridge**

9411H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	411.80	38.80	Forteo [LY]

## NERVOUS SYSTEM

### ANALGESICS

#### OPIOIDS

*Natural opium alkaloids*

#### CODEINE

**codeine phosphate 30 mg tablet, 20**

1214X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	20.50	21.71	Fawns and McAllan Proprietary Limited [FM]

#### CODEINE

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**codeine phosphate 30 mg tablet, 20**

5063L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	20.50	21.71	Fawns and McAllan Proprietary Limited [FM]

#### HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

8421F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	33.36	34.57	Dilaudid-HP [MF]

**hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules**

8420E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	28.53	29.74	Dilaudid [MF]

#### HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**hydromorphone hydrochloride 8 mg tablet, 20**

5117H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	31.37	32.58	Dilaudid [MF]

**hydromorphone hydrochloride 4 mg tablet, 20**

5116G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	22.96	24.17	Dilaudid [MF]

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

5132D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	69.31	38.80	Dilaudid [MF]

**hydromorphone hydrochloride 2 mg tablet, 20**

5115F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	20.69	21.90	Dilaudid [MF]

▪ **HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**hydromorphone hydrochloride 8 mg tablet, 20**

8543P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	31.37	32.58	Dilaudid [MF]

**hydromorphone hydrochloride 4 mg tablet, 20**

8542N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	22.96	24.17	Dilaudid [MF]

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

8424J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	69.31	38.80	Dilaudid [MF]

**hydromorphone hydrochloride 2 mg tablet, 20**

8541M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	20.69	21.90	Dilaudid [MF]

▪ **HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**hydromorphone hydrochloride 8 mg modified release tablet, 14**

9406C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	36.64	37.85	Jurnista [JC]

**hydromorphone hydrochloride 4 mg modified release tablet, 14**

9299K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	32.12	33.33	Jurnista [JC]

**hydromorphone hydrochloride 64 mg modified release tablet, 14**

9409F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	135.22	38.80	Jurnista [JC]

**hydromorphone hydrochloride 32 mg modified release tablet, 14**

9408E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	82.83	38.80	Jurnista [JC]

**hydromorphone hydrochloride 16 mg modified release tablet, 14**

9407D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	51.33	38.80	Jurnista [JC]

**▪ MORPHINE**

**Caution** The risk of drug dependence is high.

**morphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules**

10869C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	30.23	31.44	Morphine Juno [JU]

**morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules**

1647Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.92	25.13	Hospira Pty Limited [PF]

**morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules**

10874H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.78	24.99	Morphine Juno [JU]

**morphine hydrochloride 100 mg/5 mL injection, 5 x 5 mL ampoules**

10878M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	40.98	38.80	Morphine Juno [JU]

**morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules**

1607N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	42.74	38.80	Hospira Pty Limited [PF]

**morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules**

1645N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	21.82	23.03	Hospira Pty Limited [PF]

**▪ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules**

5170D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	23.92	25.13	Hospira Pty Limited [PF]

**morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules**

10858L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	23.78	24.99	Morphine Juno [JU]

**morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules**

5169C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	21.82	23.03	Hospira Pty Limited [PF]

**▪ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

10864T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	20.42	21.63	<sup>a</sup> Morphine Juno [JU]

**morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules**

1644M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	20.42	21.63	<sup>a</sup> Hospira Pty Limited [PF]

▪ **MORPHINE**

**Caution** The risk of drug dependence is high.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be due to cancer, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 200 mg modified release tablet, 28**

8453X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	116.58	38.80	MS Contin [MF]

**morphine sulfate 200 mg modified release granules, 28 sachets**

8454Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	154.66	38.80	MS Contin Suspension 200 mg [MF]

▪ **MORPHINE**

**Caution** The risk of drug dependence is high.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be due to cancer, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 20 mg tablet, 20**

8670H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	19.43	20.64	Sevredol [MF]

**morphine sulfate 10 mg tablet, 20**

8669G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	18.61	19.82	Sevredol [MF]

▪ **MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

10863R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	20.42	21.63	<sup>a</sup> Morphine Juno [JU]

**morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules**

5168B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	20.42	21.63	<sup>a</sup> Hospira Pty Limited [PF]

▪ **MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine hydrochloride 5 mg/mL oral liquid, 200 mL**

2123R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	25.93	27.14	Ordine 5 [MF]

**morphine hydrochloride 10 mg/mL oral liquid, 200 mL**

2124T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	29.52	30.73	Ordine 10 [MF]

**morphine hydrochloride 2 mg/mL oral liquid, 200 mL**

2122Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.84	25.05	Ordine 2 [MF]

**morphine sulfate 30 mg tablet, 20**

1646P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.36	19.57	Anamorph [RW]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- chronic severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine Sachet containing controlled release granules for oral suspension, 30 mg per sachet, 28**

8146R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	62.23	38.80	MS Contin Suspension 30 mg [MF]

**morphine sulfate 60 mg modified release capsule, 14**

8492Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	37.35	38.56	MS Mono [MF]

**morphine sulfate 30 mg modified release capsule, 14**

8491X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.22	28.43	MS Mono [MF]

**morphine Capsule 100 mg (containing sustained release pellets), 28**

2841M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	69.86	38.80	Kapanol [YN]

**morphine sulfate 30 mg modified release tablet, 28**

1654C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	37.37	38.58	<sup>a</sup> Momex SR 30 [RW] <sup>a</sup> MORPHINE MR APOTEX [TX] <sup>a</sup> MS Contin [MF]	<sup>a</sup> Morphine MR AN [EA] <sup>a</sup> Morphine MR Mylan [AF]

**morphine sulfate 10 mg modified release tablet, 28**

1653B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	23.59	24.80	<sup>a</sup> Momex SR 10 [RW] <sup>a</sup> MORPHINE MR APOTEX [TX] <sup>a</sup> MS Contin [MF]	<sup>a</sup> Morphine MR AN [EA] <sup>a</sup> Morphine MR Mylan [AF]

**morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28**

8305D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	69.32	38.80	MS Contin Suspension 60 mg [MF]

**morphine sulfate 120 mg modified release capsule, 14**

8494C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	54.94	38.80	MS Mono [MF]

**morphine sulfate 15 mg modified release tablet, 28**

8489T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.23	28.44	MS Contin [MF]

**morphine sulfate 5 mg modified release tablet, 28**

8035X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	21.47	22.68	MS Contin [MF]

**morphine sulfate 100 mg modified release granules, 28 sachets**

8306E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	84.32	38.80	MS Contin Suspension 100 mg [MF]

**morphine sulfate 20 mg modified release granules, 28 sachets**

8490W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	60.61	38.80	MS Contin Suspension 20 mg [MF]

**morphine sulfate 100 mg modified release tablet, 28**

1656E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	71.72	38.80	<sup>a</sup> Momex SR 100 [RW] <sup>a</sup> MORPHINE MR APOTEX [TX] <sup>a</sup> MS Contin [MF]	<sup>a</sup> Morphine MR AN [EA] <sup>a</sup> Morphine MR Mylan [AF]

**morphine Capsule 10 mg (containing sustained release pellets), 28**

8349K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.58	24.79	Kapanol [YN]

**morphine sulfate 60 mg modified release tablet, 28**

1655D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	54.95	38.80	<sup>a</sup> Momex SR 60 [RW] <sup>a</sup> MORPHINE MR APOTEX [TX] <sup>a</sup> MS Contin [MF]	<sup>a</sup> Morphine MR AN [EA] <sup>a</sup> Morphine MR Mylan [AF]

**morphine Capsule 20 mg (containing sustained release pellets), 28**

2839K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.91	29.12	Kapanol [YN]

**morphine sulfate 90 mg modified release capsule, 14**

8493B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	42.18	38.80	MS Mono [MF]

**morphine Capsule 50 mg (containing sustained release pellets), 28**

2840L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	43.82	38.80	Kapanol [YN]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine hydrochloride 5 mg/mL oral liquid, 200 mL**

5238Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	25.93	27.14	Ordine 5 [MF]

**morphine hydrochloride 10 mg/mL oral liquid, 200 mL**

5239R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	29.52	30.73	Ordine 10 [MF]

**morphine hydrochloride 2 mg/mL oral liquid, 200 mL**

5237P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	23.84	25.05	Ordine 2 [MF]

**morphine sulfate 30 mg tablet, 20**

5163R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	18.36	19.57	Anamorph [RW]

**■ OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

8644Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.34	28.55	OxyNorm Liquid 1mg/mL [MF]

**oxycodone 30 mg suppository, 12**

2481N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	46.45	38.80	Proladone [PL]

**oxycodone hydrochloride 5 mg capsule, 20**

8464L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	16.42	17.63	OxyNorm [MF]

**oxycodone hydrochloride 10 mg capsule, 20**

8501K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.70	19.91	OxyNorm [MF]

**oxycodone hydrochloride 5 mg tablet, 20**

2622B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.42	17.63	<sup>a</sup> Endone [QA]	<sup>a</sup> Mayne Pharma Oxycodone IR [YN]
						<sup>a</sup> Oxycodone Aspen [FM]	

**oxycodone hydrochloride 20 mg capsule, 20**

8502L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.14	23.35	OxyNorm [MF]

**■ OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

5190E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	27.34	28.55	OxyNorm Liquid 1mg/mL [MF]

**oxycodone 30 mg suppository, 12**

5194J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	46.45	38.80	Proladone [PL]

**oxycodone hydrochloride 5 mg capsule, 20**

5191F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.42	17.63	OxyNorm [MF]

**oxycodone hydrochloride 10 mg capsule, 20**

5197M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	18.70	19.91	OxyNorm [MF]

**oxycodone hydrochloride 5 mg tablet, 20**

5195K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.42	17.63	<sup>a</sup> Endone [QA]	<sup>a</sup> Mayne Pharma Oxycodone IR [YN]
						<sup>a</sup> Oxycodone Aspen [FM]	

▪ **OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** OxyContin and Novacodone modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 20 mg modified release tablet, 28**

8386J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	37.36	38.57	<sup>a</sup> Novacodone [HX] <sup>a</sup> OxyContin [MF]	<sup>a</sup> Oxycodone Sandoz [SZ]

**oxycodone hydrochloride 40 mg modified release tablet, 28**

8387K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	54.94	38.80	<sup>a</sup> Novacodone [HX] <sup>a</sup> OxyContin [MF]	<sup>a</sup> Oxycodone Sandoz [SZ]

**oxycodone hydrochloride 80 mg modified release tablet, 28**

8388L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	80.99	38.80	<sup>a</sup> Novacodone [HX] <sup>a</sup> OxyContin [MF]	<sup>a</sup> Oxycodone Sandoz [SZ]

**oxycodone hydrochloride 10 mg modified release tablet, 28**

8385H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	27.23	28.44	<sup>a</sup> Novacodone [HX] <sup>a</sup> OxyContin [MF]	<sup>a</sup> Oxycodone Sandoz [SZ]

▪ **OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or

- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 15 mg modified release tablet, 28**

9399Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	33.34	34.55	OxyContin [MF]

**oxycodone hydrochloride 30 mg modified release tablet, 28**

9400R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	46.92	38.80	OxyContin [MF]

**OXYCODONE + NALOXONE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- chronic severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28**

8934F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	32.83	34.04	Targin 10/5mg [MF]

**oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28**

8000C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	31.70	32.91	Targin 5/2.5mg [MF]

**oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28**

10776E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.96	25.17	Targin 2.5/1.25 mg [MF]

**oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28**

11111T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	94.36	38.80	Targin 80/40 [MF]

**oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28**

10758F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	53.47	38.80	Targin 30/15 mg [MF]

**oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28**

8936H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	72.42	38.80	Targin 40/20mg [MF]

**oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28**

8935G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	47.32	38.80	Targin 20/10mg [MF]

**oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28**

11102H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	79.72	38.80	Targin 60/30 [MF]

**oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28**

10757E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	37.18	38.39	Targin 15/7.5mg [MF]

*Phenylpiperidine derivatives*

▪ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**fentanyl 12 microgram/hour patch, 5**

5265D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.56	23.77	<sup>a</sup> Denpax [AF]

**fentanyl 12 microgram/hour patch, 5**

5437E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	22.56	23.77	<sup>a</sup> Dutran 12 [EA]	<sup>a</sup> Fenpatch 12 [ZP]

**fentanyl 12 microgram/hour patch, 5**

8878G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	22.56	23.77	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 12 [JC]

▪ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**fentanyl 25 microgram/hour patch, 5**

5277R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.86	26.07	<sup>a</sup> Denpax [AF]

**fentanyl 25 microgram/hour patch, 5**

5438F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	24.86	26.07	<sup>a</sup> Dutran 25 [EA]	<sup>a</sup> Fenpatch 25 [ZP]

**fentanyl 25 microgram/hour patch, 5**

8891Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	24.86	26.07	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 25 [JC]

▪ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**fentanyl 50 microgram/hour patch, 5**

5278T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	33.88	35.09	<sup>a</sup> Denpax [AF]

**fentanyl 50 microgram/hour patch, 5**

5439G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	33.88	35.09	<sup>a</sup> Dutran 50 [EA]	<sup>a</sup> Fenpatch 50 [ZP]

**fentanyl 50 microgram/hour patch, 5**

8892B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	33.88	35.09	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 50 [JC]

▪ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**fentanyl 75 microgram/hour patch, 5**

5279W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	41.21	38.80	<sup>a</sup> Denpax [AF]

**fentanyl 75 microgram/hour patch, 5**

5440H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	41.21	38.80	<sup>a</sup> Dutran 75 [EA]	<sup>a</sup> Fenpatch 75 [ZP]

**fentanyl 75 microgram/hour patch, 5**

8893C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	41.21	38.80	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 75 [JC]

▪ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**fentanyl 100 microgram/hour patch, 5**

5280X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	47.73	38.80	<sup>a</sup> Denpax [AF]

**fentanyl 100 microgram/hour patch, 5**

5441J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	47.73	38.80	<sup>a</sup> Dutran 100 [EA]	<sup>a</sup> Fenpatch 100 [ZP]

**fentanyl 100 microgram/hour patch, 5**

8894D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	47.73	38.80	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 100 [JC]

*Diphenylpropylamine derivatives*

▪ **METHADONE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**methadone hydrochloride 10 mg tablet, 20**

1609Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	19.40	20.61	Physeptone [QA]

**methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

1606M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	49.78	38.80	Physeptone [QA]

*Oripavine derivatives*

▪ **BUPRENORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- chronic severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**buprenorphine 15 microgram/hour patch, 2**

10770W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	47.33	38.80	Norspan [MF]

**buprenorphine 40 microgram/hour patch, 2**

10746N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	81.31	38.80	Norspan [MF]

**buprenorphine 25 microgram/hour patch, 2**

10756D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	61.15	38.80	Norspan [MF]

**buprenorphine 10 microgram/hour patch, 2**

8866P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	40.24	38.80	Norspan [MF]

**buprenorphine 20 microgram/hour patch, 2**

8867Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	54.43	38.80	Norspan [MF]

**buprenorphine 30 microgram/hour patch, 2**

10755C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	67.87	38.80	Norspan [MF]

**buprenorphine 5 microgram/hour patch, 2**

8865N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	28.62	29.83	Norspan [MF]

*Opioids in combination with non-opioid analgesics*

■ **PARACETAMOL + CODEINE**

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

3316M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.44	13.65	<sup>a</sup> APO- Paracetamol/Codeine 500/30 [TX]	<sup>a</sup> Codalgin Forte [FM]
						<sup>a</sup> Codapane Forte [AL]	<sup>a</sup> Comfarol Forte [SZ]
						<sup>a</sup> Paracetamol/Codeine GH 500/30 [GQ]	<sup>a</sup> Prodeine Forte [AV]
			<sup>b</sup> 2.10	14.54	13.65	<sup>a</sup> Panadeine Forte [SW]	

■ **PARACETAMOL + CODEINE**

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol.

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

1215Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.44	13.65	<sup>a</sup> APO- Paracetamol/Codeine 500/30 [TX]	<sup>a</sup> Codalgin Forte [FM]
						<sup>a</sup> Codapane Forte [AL]	<sup>a</sup> Comfarol Forte [SZ]
						<sup>a</sup> Paracetamol/Codeine GH 500/30 [GQ]	<sup>a</sup> Prodeine Forte [AV]
			<sup>b</sup> 2.10	14.54	13.65	<sup>a</sup> Panadeine Forte [SW]	

■ **PARACETAMOL + CODEINE**

**Note** Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

**Authority required**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

8785J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	..	..	*15.13	16.34	<sup>a</sup> APO- Paracetamol/Codeine 500/30 [TX]	<sup>a</sup> Codalgin Forte [FM]
						<sup>a</sup> Codapane Forte [AL]	<sup>a</sup> Comfarol Forte [SZ]
						<sup>a</sup> Paracetamol/Codeine GH 500/30 [GQ]	<sup>a</sup> Prodeine Forte [AV]
			<sup>b</sup> 6.30	*21.43	16.34	<sup>a</sup> Panadeine Forte [SW]	

*Other opioids*

■ **TAPENTADOL**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**tapentadol 50 mg modified release tablet, 28**

10096J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	25.52	26.73	Palexia SR [CS]

**tapentadol 200 mg modified release tablet, 28**

10091D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	47.62	38.80	Palexia SR [CS]

**tapentadol 150 mg modified release tablet, 28**

10100N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	40.95	38.80	Palexia SR [CS]

**tapentadol 100 mg modified release tablet, 28**

10094G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	33.39	34.60	Palexia SR [CS]

**tapentadol 250 mg modified release tablet, 28**

10092E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	53.28	38.80	Palexia SR [CS]

▪ **TRAMADOL**

**Restricted benefit**

Pain

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

5150C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	17.43	18.64	Tramal [CS]

▪ **TRAMADOL**

**Restricted benefit**

Acute pain

**Clinical criteria:**

- The treatment must be for the short-term.

**tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

5231H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.94	15.15	<sup>a</sup> Tramadol ACT [EA] <sup>a</sup> Tramal 100 [CS]	<sup>a</sup> Tramadol Sandoz [SZ]

▪ **TRAMADOL**

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-opioid analgesics.

**Restricted benefit**

Pain

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 150 mg modified release tablet, 20**

8524P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.32	15.53	<sup>a</sup> APO-Tramadol SR [TX] <sup>a</sup> Lodam SR 150 [ZP]  <sup>a</sup> Tramadol AN SR [EA] <sup>a</sup> Tramadol SR generichealth [GQ] <sup>a</sup> Zydol SR 150 [RW]	<sup>a</sup> Chem mart Tramadol SR [CH] <sup>a</sup> Terry White Chemists Tramadol SR [TW] <sup>a</sup> Tramadol Sandoz SR [SZ] <sup>a</sup> Tramedo SR 150 [AF]
			<sup>b</sup> 5.37	19.69	15.53	<sup>a</sup> Tramal SR 150 [CS]	

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

8843K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	17.43	18.64	Tramal [CS]

**tramadol hydrochloride 100 mg modified release tablet, 20**

8523N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	13.50	14.71	<sup>a</sup> APO-Tramadol SR [TX] <sup>a</sup> GA Tramadol SR 100mg [ED] <sup>a</sup> Terry White Chemists Tramadol SR [TW] <sup>a</sup> Tramadol Sandoz SR [SZ]  <sup>a</sup> Tramedo SR 100 [AF] <sup>a</sup> Tramal SR 100 [CS]	<sup>a</sup> Chem mart Tramadol SR [CH] <sup>a</sup> Lodam SR 100 [ZP] <sup>a</sup> Tramadol AN SR [EA] <sup>a</sup> Tramadol SR generichealth [GQ] <sup>a</sup> Zydol SR 100 [RW]
			<sup>b</sup> 4.49	17.99	14.71		

**tramadol hydrochloride 200 mg modified release tablet, 20**

8525Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	15.03	16.24	<sup>a</sup> APO-Tramadol SR [TX] <sup>a</sup> GA Tramadol SR 200mg [ED]	<sup>a</sup> Chem mart Tramadol SR [CH] <sup>a</sup> Terry White Chemists Tramadol SR [TW]
						<sup>a</sup> Tramadol AN SR [EA] <sup>a</sup> Tramadol SR generichealth [GQ] <sup>a</sup> Zydol SR 200 [RW]	<sup>a</sup> Tramadol Sandoz SR [SZ] <sup>a</sup> Tramedo SR 200 [AF]
			<sup>b</sup> 6.08	21.11	16.24	<sup>a</sup> Tramal SR 200 [CS]	

**tramadol hydrochloride 50 mg modified release tablet, 20**

2527B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	14.24	15.45	Tramal SR 50 [CS]	

▪ **TRAMADOL**

**Restricted benefit**

Acute pain

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**Restricted benefit**

Chronic pain

Treatment Phase: Dose titration

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 50 mg capsule, 20**

5232J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	13.09	14.30	<sup>a</sup> APO-Tramadol [TX] <sup>a</sup> Terry White Chemists Tramadol [TW]	<sup>a</sup> Chem mart Tramadol [CH] <sup>a</sup> Tramadol AMNEAL [EF]
						<sup>a</sup> Tramadol AN [EA] <sup>a</sup> Tramadol SCP [CR] <sup>a</sup> Zydol [RW]	<sup>a</sup> Tramadol Sandoz [SZ] <sup>a</sup> Tramedo [AF]
			<sup>b</sup> 2.42	15.51	14.30	<sup>a</sup> Tramal [CS]	

▪ **TRAMADOL**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Acute pain

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 50 mg capsule, 20**

8455B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	13.09	14.30	<sup>a</sup> APO-Tramadol [TX] <sup>a</sup> Terry White Chemists Tramadol [TW]	<sup>a</sup> Chem mart Tramadol [CH] <sup>a</sup> Tramadol AMNEAL [EF]
						<sup>a</sup> Tramadol AN [EA] <sup>a</sup> Tramadol SCP [CR] <sup>a</sup> Zydol [RW]	<sup>a</sup> Tramadol Sandoz [SZ] <sup>a</sup> Tramedo [AF]
			<sup>b</sup> 2.42	15.51	14.30	<sup>a</sup> Tramal [CS]	

▪ **TRAMADOL**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Acute pain

**Clinical criteria:**

- The treatment must be for the short-term.

**tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

8582Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	13.94	15.15	<sup>a</sup> Tramadol ACT [EA] <sup>a</sup> Tramal 100 [CS]	<sup>a</sup> Tramadol Sandoz [SZ]

## ■ TRAMADOL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Restricted benefit

Chronic pain

Treatment Phase: Dose titration

### **Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

### tramadol hydrochloride 50 mg capsule, 20

8611F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	13.09	14.30	<sup>a</sup> APO-Tramadol [TX] <sup>a</sup> Terry White Chemists Tramadol [TW] <sup>a</sup> Tramadol AN [EA] <sup>a</sup> Tramadol SCP [CR] <sup>a</sup> Zydol [RW]	<sup>a</sup> Chem mart Tramadol [CH] <sup>a</sup> Tramadol AMNEAL [EF]  <sup>a</sup> Tramadol Sandoz [SZ] <sup>a</sup> Tramedo [AF]
			<sup>b</sup> 2.42	15.51	14.30	<sup>a</sup> Tramal [CS]	

## OTHER ANALGESICS AND ANTIPYRETICS

### *Salicylic acid and derivatives*

## ■ ASPIRIN

### Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

### aspirin 300 mg effervescent tablet, 96

1010E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.61	13.82	Solprin [RC]

## ■ ASPIRIN

### Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

### aspirin 300 mg effervescent tablet, 96

5018D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	12.61	13.82	Solprin [RC]

### *Anilides*

## ■ PARACETAMOL

### Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

### paracetamol 240 mg/5 mL oral liquid, 200 mL

1770E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	2	..	14.79	16.00	Panamax 240 Elixir [SW]

### paracetamol 120 mg/5 mL oral liquid, 100 mL

1747Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	2	..	13.66	14.87	Panamax [SW]

### paracetamol 500 mg tablet, 100

1746X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	12.74	13.95	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Generic Health Pty Ltd [GQ] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Parapane [AF]	<sup>a</sup> Febridol [EA] <sup>a</sup> Panamax [SW] <sup>a</sup> Paralgin [OW]

## ■ PARACETAMOL

### Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

### paracetamol 240 mg/5 mL oral liquid, 200 mL

3349G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	±1	..	..	14.79	16.00	Panamax 240 Elixir [SW]

**paracetamol 120 mg/5 mL oral liquid, 100 mL**

3348F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	13.66	14.87	Panamax [SW]

**paracetamol 500 mg tablet, 100**

5196L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.74	13.95	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Generic Health Pty Ltd [GQ] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Parapane [AF]	<sup>a</sup> Febridol [EA] <sup>a</sup> Panamax [SW] <sup>a</sup> Paralgin [OW]

▪ **PARACETAMOL**

**Restricted benefit**

Chronic arthropathies

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 500 mg tablet, 100**

5224Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	3	..	..	*16.03	17.24	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Generic Health Pty Ltd [GQ] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Parapane [AF]	<sup>a</sup> Febridol [EA] <sup>a</sup> Panamax [SW] <sup>a</sup> Paralgin [OW]

▪ **PARACETAMOL**

**Restricted benefit**

Chronic arthropathies

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 500 mg tablet, 100**

8784H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	4	..	*16.03	17.24	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Generic Health Pty Ltd [GQ] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Parapane [AF]	<sup>a</sup> Febridol [EA] <sup>a</sup> Panamax [SW] <sup>a</sup> Paralgin [OW]

▪ **PARACETAMOL**

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

**Restricted benefit**

Persistent pain

**Clinical criteria:**

- The condition must be associated with osteoarthritis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 665 mg tablet: modified release, 192**

10797G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.55	19.76	<sup>a</sup> Osteomol 665 Paracetamol [CR]

**paracetamol 665 mg modified release tablet, 96**

8814X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.55	19.76	<sup>a</sup> APOHEALTH Osteo Relief Paracetamol 665 mg [TX]	<sup>a</sup> Osteomol 665 Paracetamol [CR]

*Other analgesics and antipyretics*

▪ **PREGABALIN**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

4172

Neuropathic pain

**Clinical criteria:**

- The condition must be refractory to treatment with other drugs.

**pregabalin 75 mg capsule, 56**

2335X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	39.70	38.80	<sup>a</sup> APO-Pregabalin [TX]	<sup>a</sup> Blooms The Chemist Pregabalin [IB]
						<sup>a</sup> LYPRALIN [RW]	<sup>a</sup> Lyrica [PF]
						<sup>a</sup> Lyzalon [AF]	<sup>a</sup> Neuroccord [CR]
						<sup>a</sup> Pregabalin AMNEAL [EA]	<sup>a</sup> Pregabalin APOTEX [GX]
						<sup>a</sup> PREGABALIN-DRLA [RZ]	<sup>a</sup> Pregabalin GH [GQ]
						<sup>a</sup> Pregabalin Sandoz [SZ]	<sup>a</sup> Pregabalin-Teva [TB]

**pregabalin 300 mg capsule, 56**

2363J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	76.58	38.80	<sup>a</sup> APO-Pregabalin [TX]	<sup>a</sup> Blooms The Chemist Pregabalin [IB]
						<sup>a</sup> LYPRALIN [RW]	<sup>a</sup> Lyrica [PF]
						<sup>a</sup> Lyzalon [AF]	<sup>a</sup> Neuroccord [CR]
						<sup>a</sup> Pregabalin AMNEAL [EA]	<sup>a</sup> Pregabalin APOTEX [GX]
						<sup>a</sup> PREGABALIN-DRLA [RZ]	<sup>a</sup> Pregabalin GH [GQ]
						<sup>a</sup> Pregabalin Sandoz [SZ]	<sup>a</sup> Pregabalin-Teva [TB]

**pregabalin 150 mg capsule, 56**

2355Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	54.98	38.80	<sup>a</sup> APO-Pregabalin [TX]	<sup>a</sup> Blooms The Chemist Pregabalin [IB]
						<sup>a</sup> LYPRALIN [RW]	<sup>a</sup> Lyrica [PF]
						<sup>a</sup> Lyzalon [AF]	<sup>a</sup> Neuroccord [CR]
						<sup>a</sup> Pregabalin AMNEAL [EA]	<sup>a</sup> Pregabalin APOTEX [GX]
						<sup>a</sup> PREGABALIN-DRLA [RZ]	<sup>a</sup> Pregabalin GH [GQ]
						<sup>a</sup> Pregabalin Sandoz [SZ]	<sup>a</sup> Pregabalin-Teva [TB]

**pregabalin 25 mg capsule, 56**

2348N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.02	25.23	<sup>a</sup> APO-Pregabalin [TX]	<sup>a</sup> Blooms The Chemist Pregabalin [IB]
						<sup>a</sup> LYPRALIN [RW]	<sup>a</sup> Lyrica [PF]
						<sup>a</sup> Lyzalon [AF]	<sup>a</sup> Neuroccord [CR]
						<sup>a</sup> Pregabalin AMNEAL [EA]	<sup>a</sup> Pregabalin APOTEX [GX]
						<sup>a</sup> PREGABALIN-DRLA [RZ]	<sup>a</sup> Pregabalin GH [GQ]
						<sup>a</sup> Pregabalin Sandoz [SZ]	<sup>a</sup> Pregabalin-Teva [TB]

**ANTIMIGRAINE PREPARATIONS***Selective serotonin (5HT<sub>1</sub>) agonists***■ ELETRIPTAN**

**Caution** Selective serotonin (5HT<sub>1</sub>) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**eletriptan 40 mg tablet, 4**

5290K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.24	27.45	Relpax [PF]

**eletriptan 80 mg tablet, 4**

5291L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.24	27.45	Relpax [PF]

**■ NARATRIPTAN**

**Caution** Selective serotonin (5HT<sub>1</sub>) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**naratriptan 2.5 mg tablet, 2**

8298R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	\$2.28	*29.47	28.40	Naramig [AS]

▪ **NARATRIPTAN**

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

**naratriptan 2.5 mg tablet, 2**

9734H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*29.47	30.68	Naramig [AS]

▪ **RIZATRIPTAN**

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**rizatriptan 10 mg wafer, 2**

9313E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.91	22.12	<sup>a</sup> Maxalt [AL]	<sup>a</sup> Rizatriptan Wafers-10mg [AF]

**rizatriptan 10 mg orally disintegrating tablet, 2**

10551H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.91	22.12	<sup>a</sup> APO-Rizatriptan [TX] <sup>a</sup> MAXATAN [RW] <sup>a</sup> Rizatriptan ODT GH [GQ]	<sup>a</sup> Chem mart Rizatriptan [CH] <sup>a</sup> Rizatriptan AN ODT [EA] <sup>a</sup> Terry White Chemists Rizatriptan [TW]

**■ SUMATRIPTAN**

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**sumatriptan 20 mg/actuation nasal spray, 2 x 1 actuation**

8341B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.25	23.46	Imigran [AS]

**SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2**

8885P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	<sup>B</sup> 4.20	*20.45	17.46	<sup>a</sup> Imigran FDT [AS]

**SUMATRIPTAN Tablet 50 mg (as succinate), 2**

8144P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*16.25	17.46	<sup>a</sup> APO-Sumatriptan [TX] <sup>a</sup> Iptam [AL] <sup>a</sup> Sumatriptan Sandoz [SZ]	<sup>a</sup> Chem mart Sumatriptan [CH] <sup>a</sup> Sumatran [OW] <sup>a</sup> Terry White Chemists Sumatriptan [TW]
			<sup>B</sup> 4.20	*20.45	17.46	<sup>a</sup> Imigran [LN]	

**SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4**

10694W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	<sup>B</sup> 4.19	20.44	17.46	<sup>a</sup> Imigran FDT [AS]

**sumatriptan 50 mg tablet, 4**

1849H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.25	17.46	<sup>a</sup> APO-Sumatriptan [TX] <sup>a</sup> Iptam [AL]  <sup>a</sup> Sumatran [OW] <sup>a</sup> Sumatriptan generichealth [GQ] <sup>a</sup> Sumatriptan Sandoz [SZ]	<sup>a</sup> Chem mart Sumatriptan [CH] <sup>a</sup> Pharmacor Sumatriptan 50 [CR] <sup>a</sup> Sumatriptan AN [EA] <sup>a</sup> Sumatriptan RBX [RA]  <sup>a</sup> Terry White Chemists Sumatriptan [TW]
			<sup>B</sup> 4.19	20.44	17.46	<sup>a</sup> Imigran [LN]	

**■ ZOLMITRIPTAN**

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**zolmitriptan 2.5 mg tablet, 2**

8266C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.97	24.18	<sup>a</sup> APO-Zolmitriptan [TX]	<sup>a</sup> Zoltrip [RW]
			<sup>b</sup> 2.76	*25.73	24.18	<sup>a</sup> Zomig [AP]	

*Other antimigraine preparations*

■ **CYPROHEPTADINE**

**Note** Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Prevention of migraine

**cyproheptadine hydrochloride 4 mg tablet, 100**

1798P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.52	18.73	Periactin [AS]

■ **PIZOTIFEN**

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**pizotifen 500 microgram tablet, 100**

3074T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	24.67	25.88	Sandomigran 0.5 [AE]

■ **ANTIEPILEPTICS**

**ANTIEPILEPTICS**

*Barbiturates and derivatives*

■ **PHENOBARBITONE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Epilepsy

**phenobarbitone sodium 219 mg/mL injection, 5 x 1 mL ampoules**

2138M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	38.02	38.80	Fawns and McAllan Proprietary Limited [FM]

**phenobarbitone 30 mg tablet, 200**

1850J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	19.50	20.71	Phenobarb [RW]

■ **PRIMIDONE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**primidone 250 mg tablet, 200**

1939C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	77.64	38.80	Mysoline [LM]

*Hydantoin derivatives***■ PHENYTOIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**phenytoin sodium 100 mg capsule, 200**

1874P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	34.85	36.06	Dilantin Sodium [PF]

**phenytoin sodium 30 mg capsule, 200**

1873N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	31.08	32.29	Dilantin Sodium [PF]

**phenytoin 30 mg/5 mL oral liquid, 500 mL**

2692Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	3	..	30.81	32.02	Dilantin [PF]

**phenytoin 50 mg chewable tablet, 200**

1249R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	48.49	38.80	Dilantin Infatabs [PF]

*Succinimide derivatives***■ ETHOSUXIMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**ethosuximide 250 mg capsule, 200**

1413J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	318.33	38.80	Zarontin [IX]

**ethosuximide 250 mg/5 mL oral liquid, 200 mL**

1414K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	71.68	38.80	Zarontin [IX]

*Benzodiazepine derivatives***■ CLONAZEPAM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Epilepsy

**clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack**

1807D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	21.66	22.87	Rivotril [RO]

**■ CLONAZEPAM**

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Epilepsy

**Clinical criteria:**

- The condition must be neurologically proven.

**clonazepam 500 microgram tablet, 100**

1805B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*22.47	23.68	<sup>a</sup> Paxam 0.5 [AF]
			<sup>B</sup> 3.68	*26.15	23.68	<sup>a</sup> Rivotril [RO]

**clonazepam 2 mg tablet, 100**

1806C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*32.51	33.72	<sup>a</sup> Paxam 2 [AF]
			<sup>B</sup> 4.60	*37.11	33.72	<sup>a</sup> Rivotril [RO]

**clonazepam 2.5 mg/mL oral liquid, 10 mL**

1808E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*18.59	19.80	Rivotril [RO]

**■ NITRAZEPAM**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

2732T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*14.31	15.52	<sup>a</sup> Alodorm [AF]
			<sup>B</sup> 2.48	*16.79	15.52	<sup>a</sup> Mogadon [IA]

*Carboxamide derivatives*

**■ CARBAMAZEPINE**

**carbamazepine 400 mg modified release tablet, 200**

5037D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	49.20	38.80	Tegretol CR 400 [NV]

**CARBAMAZEPINE Tablet 100 mg, 100**

5039F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*22.85	24.06	<sup>a</sup> Carbamazepine Sandoz [SZ]
			<sup>B</sup> 3.00	*25.85	24.06	<sup>a</sup> Tegretol 100 [NV]

**CARBAMAZEPINE Tablet 200 mg, 100**

1724R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*30.73	31.94	<sup>a</sup> Carbamazepine Sandoz [SZ]
			<sup>B</sup> 2.96	*33.69	31.94	<sup>a</sup> Tegretol 200 [NV]

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

5041H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	24.07	25.28	Tegretol Liquid [NV]

**carbamazepine 200 mg modified release tablet, 200**

5038E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	31.14	32.35	Tegretol CR 200 [NV]

**■ CARBAMAZEPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**carbamazepine 400 mg modified release tablet, 200**

2431Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	49.20	38.80	Tegretol CR 400 [NV]

**CARBAMAZEPINE Tablet 100 mg, 100**

2422L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*22.85	24.06	<sup>a</sup> Carbamazepine Sandoz [SZ]
			<sup>b</sup> 3.00	*25.85	24.06	<sup>a</sup> Tegretol 100 [NV]

**CARBAMAZEPINE Tablet 200 mg, 100**

1706T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*30.73	31.94	<sup>a</sup> Carbamazepine Sandoz [SZ]
			<sup>b</sup> 2.96	*33.69	31.94	<sup>a</sup> Tegretol 200 [NV]

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

2427R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	24.07	25.28	Tegretol Liquid [NV]

**carbamazepine 200 mg modified release tablet, 200**

2426Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	31.14	32.35	Tegretol CR 200 [NV]

**■ OXCARBAZEPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5183**

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**oxcarbazepine 300 mg tablet, 100**

8585W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	104.93	38.80	Trileptal [NV]

**oxcarbazepine 60 mg/mL oral liquid, 250 mL**

8588B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*124.83	38.80	Trileptal [NV]

**oxcarbazepine 600 mg tablet, 100**

8586X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	167.89	38.80	Trileptal [NV]

**oxcarbazepine 150 mg tablet, 100**

8584T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	67.96	38.80	Trileptal [NV]

**Fatty acid derivatives****■ TIAGABINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4928**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**tiagabine 15 mg tablet, 50**

8223T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*175.57	38.80	Gabitril [OA]

**tiagabine 10 mg tablet, 50**

8222R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*125.45	38.80	Gabitril [OA]

**tiagabine 5 mg tablet, 50**

8221Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*68.27	38.80	Gabitril [OA]

■ **VALPROATE**

**Caution** There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**valproate sodium 100 mg tablet, 100**

2294R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*33.33	34.54	Epilim [SW]

**valproate sodium 200 mg enteric tablet, 100**

2289L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*22.83	24.04	<sup>a</sup> Sodium Valproate Sandoz [SZ]	<sup>a</sup> Valprease 200 [RW]
						<sup>a</sup> Valpro 200 [AF]	<sup>a</sup> Valproate Winthrop EC 200 [WA]
			<sup>b</sup> 2.00	*24.83	24.04	<sup>a</sup> Epilim EC [SW]	

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

2293Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*39.05	38.80	Epilim Liquid [SW]

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

2295T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*39.05	38.80	Epilim Syrup [SW]

**valproate sodium 500 mg enteric tablet, 100**

2290M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*34.33	35.54	<sup>a</sup> Sodium Valproate Sandoz [SZ]	<sup>a</sup> Valprease 500 [RW]
						<sup>a</sup> Valpro 500 [AF]	<sup>a</sup> Valproate Winthrop EC 500 [WA]
			<sup>b</sup> 2.00	*36.33	35.54	<sup>a</sup> Epilim EC [SW]	

■ **VIGABATRIN**

**Caution** Visual field defects have been reported with this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4929**

Epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**vigabatrin 500 mg tablet, 100**

2667J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	108.13	38.80	Sabril [SW]

**vigabatrin 500 mg powder for oral liquid, 60 sachets**

2668K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	73.90	38.80	Sabril [SW]

**Other antiepileptics****■ GABAPENTIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4928**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**gabapentin 100 mg capsule, 100**

8505P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.13	16.34	<sup>a</sup> APO-Gabapentin [TX] <sup>a</sup> Gabapentin Aspen 100 [RW] <sup>a</sup> Neurontin [PF]	<sup>a</sup> Gabacor [CR] <sup>a</sup> GAPENTIN [RF] <sup>a</sup> Nupentin 100 [AF]

**gabapentin 400 mg capsule, 100**

1835N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.50	30.71	<sup>a</sup> APO-Gabapentin [TX] <sup>a</sup> Gabapentin AN [EA] <sup>a</sup> Gabapentin GH [GQ] <sup>a</sup> GAPENTIN [RF] <sup>a</sup> Neurontin [PF]	<sup>a</sup> Gabacor [CR] <sup>a</sup> Gabapentin Aspen 400 [RW] <sup>a</sup> Gabapentin Sandoz [SZ] <sup>a</sup> GenRx Gabapentin [GX] <sup>a</sup> Nupentin 400 [AF]

**gabapentin 600 mg tablet, 100**

8559L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.31	38.80	<sup>a</sup> APO-Gabapentin [TX] <sup>a</sup> Gabapentin Aspen 600 [RW] <sup>a</sup> GenRx Gabapentin [GX] <sup>a</sup> Nupentin Tabs [AF]	<sup>a</sup> Gabapentin AN [EA] <sup>a</sup> GAPENTIN [RF] <sup>a</sup> Neurontin [PF] <sup>a</sup> Pharmacor Gabapentin 600 [CR]

**gabapentin 300 mg capsule, 100**

1834M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.59	25.80	<sup>a</sup> APO-Gabapentin [TX] <sup>a</sup> Gabapentin AN [EA] <sup>a</sup> Gabapentin GH [GQ] <sup>a</sup> GAPENTIN [RF] <sup>a</sup> Neurontin [PF]	<sup>a</sup> Gabacor [CR] <sup>a</sup> Gabapentin Aspen 300 [RW] <sup>a</sup> Gabapentin Sandoz [SZ] <sup>a</sup> GenRx Gabapentin [GX] <sup>a</sup> Nupentin 300 [AF]

**gabapentin 800 mg tablet, 100**

8389M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	50.06	38.80	<sup>a</sup> APO-Gabapentin [TX] <sup>a</sup> Gabapentin Aspen 800 [RW] <sup>a</sup> GenRx Gabapentin [GX] <sup>a</sup> Nupentin Tabs [AF]	<sup>a</sup> Gabapentin AN [EA] <sup>a</sup> GAPENTIN [RF] <sup>a</sup> Neurontin [PF] <sup>a</sup> Pharmacor Gabapentin 800 [CR]

**■ LACOSAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4271**

Intractable partial epileptic seizures

Treatment Phase: Initial

**Treatment criteria:**

- Must be treated by a neurologist.
- Clinical criteria:**
- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must be for dose titration purposes.

**Population criteria:**

- Patient must be aged 16 years or older.

**lacosamide 50 mg tablet, 14**

9333F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	30.74	31.95	Vimpat [UC]

**lacosamide 150 mg tablet, 14**

9336J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	70.04	38.80	Vimpat [UC]

**lacosamide 100 mg tablet, 14**

9334G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	50.40	38.80	Vimpat [UC]

▪ **LACOSAMIDE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4249**

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised lacosamide.

**Population criteria:**

- Patient must be aged 16 years or older.

**lacosamide 50 mg tablet, 14**

10293R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*89.71	38.80	Vimpat [UC]

▪ **LACOSAMIDE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4264**

Intractable partial epileptic seizures

Treatment Phase: Initial

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Population criteria:**

- Patient must be aged 16 years or older.

**Authority required (STREAMLINED)**

**4249**

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised lacosamide.

**Population criteria:**

- Patient must be aged 16 years or older.

**lacosamide 100 mg tablet, 56**

9335H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	168.33	38.80	Vimpat [UC]

**■ LACOSAMIDE**

**Note** No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4240**

Intractable partial epileptic seizures

Treatment Phase: Initial

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Population criteria:**

- Patient must be aged 16 years or older.

**Authority required (STREAMLINED)****4257**

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised lacosamide.

**Population criteria:**

- Patient must be aged 16 years or older.

**lacosamide 200 mg tablet, 56**

9338L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	330.20	38.80	Vimpat [UC]

**lacosamide 150 mg tablet, 56**

9337K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	248.85	38.80	Vimpat [UC]

**■ LAMOTRIGINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5138**

Epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**lamotrigine 200 mg tablet, 56**

2851C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.06	38.27	<sup>a</sup> APO-Lamotrigine [TX]	<sup>a</sup> Lamidus [RA]
						<sup>a</sup> LAMITAN [RF]	<sup>a</sup> Lamotrigine AN [EA]
						<sup>a</sup> Lamotrigine Aspen 200 [RW]	<sup>a</sup> Lamotrigine generichealth [HQ]
						<sup>a</sup> Lamotrigine GH [GQ]	<sup>a</sup> Lamotrigine Sandoz [SZ]
						<sup>a</sup> Logem [AL]	<sup>a</sup> Reedos 200 [DO]
			<sup>B</sup> 1.49	38.55	38.27	<sup>a</sup> Lamictal [AS]	

**lamotrigine 50 mg tablet, 56**

2849Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.37	21.58	<sup>a</sup> APO-Lamotrigine [TX]	<sup>a</sup> Lamidus [RA]
						<sup>a</sup> LAMITAN [RF]	<sup>a</sup> Lamotrigine AN [EA]
						<sup>a</sup> Lamotrigine Aspen 50 [RW]	<sup>a</sup> Lamotrigine GH [GQ]

<sup>a</sup> Lamotrigine Sandoz [SZ]      <sup>a</sup> Logem [AL]  
<sup>a</sup> Reedos 50 [DO]      <sup>a</sup> Sandoz Lamotrigine [HX]  
<sup>a</sup> Lamictal [AS]

<sup>B</sup>1.44      21.81      21.58

**lamotrigine 25 mg tablet, 56**

2848X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.66	17.87	<sup>a</sup> APO-Lamotrigine [TX] <sup>a</sup> LAMITAN [RF] <sup>a</sup> Lamotrigine Aspen 25 [RW] <sup>a</sup> Lamotrigine Sandoz [SZ] <sup>a</sup> Reedos 25 [DO]	<sup>a</sup> Lamidus [RA] <sup>a</sup> Lamotrigine AN [EA] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]
			<sup>B</sup> 1.61	18.27	17.87	<sup>a</sup> Lamictal [AS]	

**lamotrigine 100 mg tablet, 56**

2850B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	26.54	27.75	<sup>a</sup> APO-Lamotrigine [TX] <sup>a</sup> LAMITAN [RF] <sup>a</sup> Lamotrigine Aspen 100 [RW]  <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL]	<sup>a</sup> Lamidus [RA] <sup>a</sup> Lamotrigine AN [EA] <sup>a</sup> Lamotrigine generichealth [HQ]  <sup>a</sup> Lamotrigine Sandoz [SZ] <sup>a</sup> Reedos 100 [DO]
			<sup>B</sup> 1.51	28.05	27.75	<sup>a</sup> Lamictal [AS]	

**lamotrigine 5 mg tablet, 56**

8063J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.41	18.62	<sup>a</sup> Lamictal [AS]	<sup>a</sup> Lamotrigine Aspen 5 [RW]

**LEVETIRACETAM**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4928**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**levetiracetam 250 mg tablet, 60**

8654L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.62	23.83	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kerron 250 [DO] <sup>a</sup> Levactam [ER] <sup>a</sup> Levetiracetam AN [EA] <sup>a</sup> Levetiracetam SZ [SZ]	<sup>a</sup> Keppra [UC] <sup>a</sup> Kevtam [AF] <sup>a</sup> Levetacetam 250 [RZ] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levi 250 [RW]

**levetiracetam 1 g tablet, 60**

8656N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	43.09	38.80	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kerron 1000 [DO] <sup>a</sup> Levactam [ER] <sup>a</sup> Levetiracetam AN [EA] <sup>a</sup> Levetiracetam SZ [SZ] <sup>a</sup> Levitaccord [RA]	<sup>a</sup> Keppra [UC] <sup>a</sup> Kevtam 1000 [AF] <sup>a</sup> Levetacetam 1000 [RZ] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levi 1000 [RW]

**levetiracetam 500 mg tablet, 60**

8655M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	30.29	31.50	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kerron 500 [DO] <sup>a</sup> Levactam [ER] <sup>a</sup> Levetiracetam AN [EA] <sup>a</sup> Levetiracetam SZ [SZ]	<sup>a</sup> Keppra [UC] <sup>a</sup> Kevtam [AF] <sup>a</sup> Levetacetam 500 [RZ] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levi 500 [RW]

**LEVETIRACETAM**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5215**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of levetiracetam.

**levetiracetam 100 mg/mL oral liquid, 300 mL**

9169N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	73.45	38.80	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kerron [DO]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levetiracetam-AFT [AE]

**■ PERAMPANEL****Authority required (STREAMLINED)****4656**

Intractable partial epileptic seizures

Treatment Phase: Initial

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Treatment criteria:**

- Must be treated by a neurologist.

**perampanel 2 mg tablet, 7**

10157N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*52.47	38.80	Fycompa [EI]

**■ PERAMPANEL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4658**

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**perampanel 8 mg tablet, 28**

10160R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	347.33	38.80	Fycompa [EI]

**perampanel 10 mg tablet, 28**

10151G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	347.33	38.80	Fycompa [EI]

**perampanel 4 mg tablet, 28**

10162W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	176.58	38.80	Fycompa [EI]

**perampanel 12 mg tablet, 28**

10159Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	347.33	38.80	Fycompa [EI]

**perampanel 6 mg tablet, 28**

10163X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	261.72	38.80	Fycompa [EI]

**■ SULTHIAME****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**sulthiame 50 mg tablet, 200**

2099L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	76.77	38.80	Ospolot [PL]

**sulthiame 200 mg tablet, 200**

2100M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	183.58	38.80	Ospolot [PL]

■ **TOPIRAMATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5516**

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**topiramate 100 mg tablet, 60**

8165R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.58	29.79	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topamax [JC] <sup>a</sup> Topiramate GH [GQ]	<sup>a</sup> Epiramax 100 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> Topiramate AN [EA] <sup>a</sup> Topiramate Sandoz [SZ]

**topiramate 200 mg tablet, 60**

8166T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.48	38.80	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topamax [JC] <sup>a</sup> Topiramate GH [GQ]	<sup>a</sup> Epiramax 200 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> Topiramate AN [EA] <sup>a</sup> Topiramate Sandoz [SZ]

■ **TOPIRAMATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5173**

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

**topiramate 25 mg capsule, 60**

8372P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.75	18.96	Topamax Sprinkle [JC]

**topiramate 15 mg capsule, 60**

8371N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.18	20.39	Topamax Sprinkle [JC]

**topiramate 50 mg capsule, 60**

8520K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.19	23.40	Topamax Sprinkle [JC]

■ **TOPIRAMATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5516**

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Authority required (STREAMLINED)**

**5325**

Migraine

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

**topiramate 50 mg tablet, 60**

8164Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.21	23.42	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topamax [JC] <sup>a</sup> Topiramate GH [GQ]	<sup>a</sup> Epiramax 50 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> Topiramate AN [EA] <sup>a</sup> Topiramate Sandoz [SZ]

**topiramate 25 mg tablet, 60**

8163P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.86	19.07	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topamax [JC] <sup>a</sup> Topiramate GH [GQ]	<sup>a</sup> Epiramax 25 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> Topiramate AN [EA] <sup>a</sup> Topiramate Sandoz [SZ]

▪ **ZONISAMIDE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4928**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**zonisamide 50 mg capsule, 56**

9389E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	30.04	31.25	<sup>a</sup> APO-Zonisamide [TX]	<sup>a</sup> Zonegran [SA]

**zonisamide 100 mg capsule, 56**

9390F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*74.23	38.80	<sup>a</sup> APO-Zonisamide [TX]	<sup>a</sup> Zonegran [SA]

**zonisamide 25 mg capsule, 56**

9388D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.45	23.66	<sup>a</sup> APO-Zonisamide [TX]	<sup>a</sup> Zonegran [SA]

▪ **ANTI-PARKINSON DRUGS**

**ANTICHOLINERGIC AGENTS**

*Tertiary amines*

## ■ BENZHEXOL

### benzhexol hydrochloride 5 mg tablet, 200

1110K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	24.50	25.71	Artane [RW]

### benzhexol hydrochloride 2 mg tablet, 200

1109J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18.85	20.06	Artane [RW]

## ■ BIPERIDEN

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### biperiden hydrochloride 2 mg tablet, 100

2544X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*23.05	24.26	Akineton [GH]

### Ethers of tropine or tropine derivatives

## ■ BENZATROPINE

### benzotropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials

10013B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	263.28	38.80	Benztropine Omega [FK]

### benzotropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials

10027R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	263.28	38.80	Benztropine Omega [FK]

### benzotropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules

3038X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	95.01	38.80	Cogentin [FK]

### benzotropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules

5031T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	95.01	38.80	Cogentin [FK]

### benzotropine mesilate 2 mg tablet, 60

2362H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18.28	19.49	Benztrop [PL]

## DOPAMINERGIC AGENTS

### Dopa and dopa derivatives

## ■ LEVODOPA + BENSERAZIDE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### levodopa 50 mg + benserazide 12.5 mg capsule, 100

2227F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.79	26.00	Madopar 62.5 [RO]

### LEVODOPA with BENSERAZIDE Dispersible tablet 100 mg-25 mg, 100

8219N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	37.94	38.80	Madopar Rapid 125 [RO]

### levodopa 200 mg + benserazide 50 mg tablet, 100

2228G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	48.23	38.80	Madopar [RO]

**levodopa 100 mg + benserazide 25 mg capsule, 100**

2225D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	37.94	38.80	Madopar 125 [RO]

**levodopa 100 mg + benserazide 25 mg tablet, 100**

2229H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	37.94	38.80	Madopar 125 [RO]

**levodopa 100 mg + benserazide 25 mg modified release capsule, 100**

2231K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	40.61	38.80	Madopar HBS [RO]

**levodopa 200 mg + benserazide 50 mg capsule, 100**

2226E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	48.23	38.80	Madopar [RO]

**LEVODOPA with BENSERAZIDE Dispersible tablet 50 mg-12.5 mg, 100**

8218M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.79	26.00	Madopar Rapid 62.5 [RO]

**■ LEVODOPA + CARBIDOPA ANHYDROUS****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100**

1242J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	38.80	38.80	<sup>a</sup> Kinson [AF]
			<sup>b</sup> 4.85	43.65	38.80	<sup>a</sup> Sinemet 100/25 [MK]

**levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100**

1245M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	45.26	38.80	Sinemet [MK]

**■ LEVODOPA + CARBIDOPA ANHYDROUS****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

**levodopa 200 mg + carbidopa anhydrous 50 mg modified release tablet, 100**

1255C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	66.95	38.80	Sinemet CR [MK]

**■ LEVODOPA + CARBIDOPA ANHYDROUS**

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5473**

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

8970D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*11685.47	38.80	Duodopa [VE]

**▪ LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

**levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100**

9345W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*345.87	38.80	Stalevo 125/31.25/200mg [NV]

**levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100**

9292C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*393.13	38.80	Stalevo 200/50/200mg [NV]

**levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100**

8799D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*364.49	38.80	Stalevo 150/37.5/200mg [NV]

**levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100**

8797B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*302.31	38.80	Stalevo 50/12.5/200mg [NV]

**levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100**

8798C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*333.41	38.80	Stalevo 100/25/200mg [NV]

**levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100**

9344T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*316.01	38.80	Stalevo 75/18.75/200mg [NV]

*Adamantane derivatives*

**▪ AMANTADINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must not be drug induced.

**amantadine hydrochloride 100 mg capsule, 100**

3016R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	42.81	38.80	Symmetrel 100 [NV]

*Dopamine agonists*

**▪ BROMOCRIPTINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson disease

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

1443Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*32.83	34.04	Parlodel [SZ]

■ **CABERGOLINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**cabergoline 2 mg tablet, 30**

8394T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	76.11	38.80	Cabaser [PF]

**cabergoline 1 mg tablet, 30**

8393R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.60	38.80	Cabaser [PF]

■ **PRAMIPEXOLE**

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**pramipexole hydrochloride monohydrate 250 microgram tablet, 100**

9152Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	28.97	30.18	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Pramipexole GH [GQ] <sup>a</sup> Simipex 0.25 [RW]	<sup>a</sup> Pramipexole AN [EA] <sup>a</sup> Sifrol [BY] <sup>a</sup> Simpral [AF]

**pramipexole hydrochloride monohydrate 125 microgram tablet, 30**

9151P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	13.82	15.03	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Pramipexole GH [GQ] <sup>a</sup> Simipex 0.125 [RW]	<sup>a</sup> Pramipexole AN [EA] <sup>a</sup> Sifrol [BY] <sup>a</sup> Simpral [AF]

**pramipexole hydrochloride monohydrate 1 mg tablet, 100**

9153R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	89.14	38.80	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Pramipexole GH [GQ]	<sup>a</sup> Pramipexole AN [EA] <sup>a</sup> Sifrol [BY]

<sup>a</sup> Simipex 1 [RW]

<sup>a</sup> Simpral [AF]

■ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**pramipexole hydrochloride monohydrate 375 microgram modified release tablet, 30**

3418X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.85	20.06	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> Sifrol ER [BY]	<sup>a</sup> Pramipexole XR GP [AF] <sup>a</sup> SIMIPEX XR [RW]

**pramipexole hydrochloride monohydrate 1.5 mg modified release tablet, 30**

3420B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.63	38.80	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> Sifrol ER [BY]	<sup>a</sup> Pramipexole XR GP [AF] <sup>a</sup> SIMIPEX XR [RW]

**pramipexole hydrochloride monohydrate 2.25 mg modified release tablet, 30**

5143Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	56.89	38.80	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> Sifrol ER [BY]	<sup>a</sup> Pramipexole XR GP [AF] <sup>a</sup> SIMIPEX XR [RW]

**pramipexole hydrochloride monohydrate 4.5 mg modified release tablet, 30**

3422D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	111.03	38.80	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> Sifrol ER [BY]	<sup>a</sup> Pramipexole XR GP [AF] <sup>a</sup> SIMIPEX XR [RW]

**pramipexole hydrochloride monohydrate 750 microgram modified release tablet, 30**

3419Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.36	27.57	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> Sifrol ER [BY]	<sup>a</sup> Pramipexole XR GP [AF] <sup>a</sup> SIMIPEX XR [RW]

**pramipexole hydrochloride monohydrate 3 mg modified release tablet, 30**

3421C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	77.72	38.80	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> Sifrol ER [BY]	<sup>a</sup> Pramipexole XR GP [AF] <sup>a</sup> SIMIPEX XR [RW]

**pramipexole hydrochloride monohydrate 3.75 mg modified release tablet, 30**

5145T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	92.98	38.80	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> Sifrol ER [BY]	<sup>a</sup> Pramipexole XR GP [AF] <sup>a</sup> SIMIPEX XR [RW]

■ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Primary severe restless legs syndrome

**Clinical criteria:**

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and

- (b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and
- (c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and
- (d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

**pramipexole hydrochloride monohydrate 250 microgram tablet, 100**

9394K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	28.97	30.18	Sifrol [BY]

**pramipexole hydrochloride monohydrate 125 microgram tablet, 30**

9393J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	13.82	15.03	Sifrol [BY]

**▪ ROTIGOTINE****Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 6 mg/24 hours patch, 28**

2410W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	108.51	38.80	Neupro [UC]

**rotigotine 4 mg/24 hours patch, 28**

2384L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	96.94	38.80	Neupro [UC]

**rotigotine 8 mg/24 hours patch, 28**

11140H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	119.43	38.80	Neupro [UC]

**▪ ROTIGOTINE****Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 2 mg/24 hours patch, 28**

2385M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	75.48	38.80	Neupro [UC]

***Monoamine oxidase B inhibitors*****▪ RASAGILINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Parkinson disease

**RASAGILINE Tablet 1 mg (as mesilate), 30**

1952R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	115.79	38.80	Azilect [TB]

**▪ SELEGILINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Late stage Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**selegiline hydrochloride 5 mg tablet, 100**

1973W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	53.13	38.80	Eldepryl [AS]

*Other dopaminergic agents*

▪ **ENTACAPONE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**entacapone 200 mg tablet, 100**

8367J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*257.89	38.80	Comtan [NV]

▪ **PSYCHOLEPTICS**

**ANTIPSYCHOTICS**

*Phenothiazines with aliphatic side-chain*

▪ **CHLORPROMAZINE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules**

1195X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.70	23.91	Largactil [SW]

**chlorpromazine hydrochloride 10 mg tablet, 100**

1196Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.77	15.98	Largactil [SW]

**chlorpromazine hydrochloride 25 mg tablet, 100**

1197B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.28	16.49	Largactil [SW]

**chlorpromazine hydrochloride 100 mg tablet, 100**

1199D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.19	21.40	Largactil [SW]

**chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL**

1201F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	16.35	17.56	Largactil [SW]

*Phenothiazines with piperazine structure*

▪ **TRIFLUOPERAZINE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**trifluoperazine 5 mg tablet, 100**

2186C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	25.22	26.43	Stelazine [GH]

**trifluoperazine 1 mg tablet, 100**

2185B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.42	20.63	Stelazine [GH]

**trifluoperazine 2 mg tablet, 100**

2386N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.50	24.71	Stelazine [GH]

*Phenothiazines with piperidine structure***PERICYAZINE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**pericyazine 2.5 mg tablet, 100**

3052P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.62	15.83	Neulactil [SW]

**pericyazine 10 mg tablet, 100**

3053Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.35	19.56	Neulactil [SW]

*Butyrophenone derivatives***HALOPERIDOL****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**haloperidol 2 mg/mL oral liquid, 100 mL**

2763K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.68	23.89	Serenace [QA]

**haloperidol 5 mg tablet, 50**

2770T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.61	15.82	Serenace [QA]

**haloperidol 1.5 mg tablet, 100**

2767P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.80	16.01	Serenace [QA]

**haloperidol 500 microgram tablet, 100**

2761H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.51	15.72	Serenace [QA]

**haloperidol 5 mg/mL injection, 10 x 1 mL ampoules**

2768Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.20	25.41	Serenace [QA]

**HALOPERIDOL DECANOATE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL vials**

2765M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	30.34	31.55	Haldol decanoate [JC]

**haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules**

2766N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	49.67	38.80	Haldol decanoate [JC]

*Indole derivatives***LURASIDONE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4246**

Schizophrenia

**lurasidone hydrochloride 80 mg tablet, 30**

10529E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	144.35	38.80	Latuda [SE]

**lurasidone hydrochloride 40 mg tablet, 30**

10526B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	77.72	38.80	Latuda [SE]

▪ **ZIPRASIDONE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4246**

Schizophrenia

**Authority required (STREAMLINED)**

**5742**

Acute mania or mixed episodes

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**ziprasidone 80 mg capsule, 60**

9073M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	189.38	38.80	<sup>a</sup> APO-Ziprasidone [TX] <sup>a</sup> ZIPROX [RW]	<sup>a</sup> Zeldox [PF]

**ziprasidone 60 mg capsule, 60**

9072L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	144.63	38.80	<sup>a</sup> APO-Ziprasidone [TX] <sup>a</sup> ZIPROX [RW]	<sup>a</sup> Zeldox [PF]

**ziprasidone 40 mg capsule, 60**

9071K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	100.44	38.80	<sup>a</sup> APO-Ziprasidone [TX] <sup>a</sup> ZIPROX [RW]	<sup>a</sup> Zeldox [PF]

**ziprasidone 20 mg capsule, 60**

9070J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	55.69	38.80	<sup>a</sup> APO-Ziprasidone [TX] <sup>a</sup> ZIPROX [RW]	<sup>a</sup> Zeldox [PF]

*Thioxanthene derivatives*

▪ **FLUPENTHIXOL DECANOATE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**flupenthixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules**

2255Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.34	24.55	Fluanxol Depot [LU]

**flupenthixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules**

2257T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	48.44	38.80	Fluanxol Concentrated Depot [LU]

▪ **ZUCLOPENTHIXOL DECANOATE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules

8097E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	29.19	30.40	Clopixol Depot [LU]

### *Diazepines, oxazepines, thiazepines and oxepines*

#### ■ ASENAPINE

##### Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

##### Authority required (STREAMLINED)

##### 4246

Schizophrenia

##### Authority required (STREAMLINED)

##### 5773

Acute mania or mixed episodes

##### Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.

##### Authority required (STREAMLINED)

##### 5719

Bipolar I disorder

##### Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

### asenapine 10 mg sublingual wafer, 60

5141N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	229.26	38.80	Saphris [LU]

### asenapine 5 mg sublingual wafer, 60

5140M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	141.19	38.80	Saphris [LU]

#### ■ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

##### Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

##### Authority required (STREAMLINED)

##### 5856

Schizophrenia

##### Authority required (STREAMLINED)

##### 5869

Bipolar I disorder

##### Clinical criteria:

- The treatment must be maintenance therapy.

### olanzapine 2.5 mg tablet, 28

1024X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	13.86	15.07	<sup>a</sup> Olanzapine generichealth 2.5 [GQ]

### olanzapine 2.5 mg tablet, 28

8170B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.86	15.07	<sup>a</sup> APO-Olanzapine [TX]	<sup>a</sup> Chem mart Olanzapine [CH]
						<sup>a</sup> Olanzacor 2.5 [CR]	<sup>a</sup> Olanzapine AN [EA]
						<sup>a</sup> Olanzapine-DRLA [RZ]	<sup>a</sup> Olanzapine RBX [RA]
						<sup>a</sup> Olanzapine Sandoz [SZ]	<sup>a</sup> Ozin 2.5 [DO]
						<sup>a</sup> PRYZEX [RW]	<sup>a</sup> Terry White Chemists Olanzapine [TW]
						<sup>a</sup> Zypine [AF]	

<sup>B</sup>3.00 16.86 15.07 <sup>a</sup> Zyprexa [LY]

■ OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5856**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 5 mg tablet, 28**

1037N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.57	17.78	<sup>a</sup> Olanzapine generichealth 5 [GQ]

**olanzapine 5 mg tablet, 28**

8185T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.57	17.78	<sup>a</sup> APO-Olanzapine [TX] <sup>a</sup> Olanzacor 5 [CR] <sup>a</sup> Olanzapine-DRLA [RZ] <sup>a</sup> Olanzapine Sandoz [SZ] <sup>a</sup> PRYZEX [RW]  <sup>a</sup> Zypine [AF]	<sup>a</sup> Chem mart Olanzapine [CH] <sup>a</sup> Olanzapine AN [EA] <sup>a</sup> Olanzapine RBX [RA] <sup>a</sup> Ozin 5 [DO] <sup>a</sup> Terry White Chemists Olanzapine [TW]
			<sup>B</sup> 3.00	19.57	17.78	<sup>a</sup> Zyprexa [LY]	

■ OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5856**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 7.5 mg tablet, 28**

1041T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.40	20.61	<sup>a</sup> Olanzapine generichealth 7.5 [GQ]

**olanzapine 7.5 mg tablet, 28**

8186W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.40	20.61	<sup>a</sup> APO-Olanzapine [TX] <sup>a</sup> Olanzacor 7.5 [CR] <sup>a</sup> Olanzapine-DRLA [RZ] <sup>a</sup> Olanzapine Sandoz [SZ] <sup>a</sup> PRYZEX [RW]  <sup>a</sup> Zypine [AF]	<sup>a</sup> Chem mart Olanzapine [CH] <sup>a</sup> Olanzapine AN [EA] <sup>a</sup> Olanzapine RBX [RA] <sup>a</sup> Ozin 7.5 [DO] <sup>a</sup> Terry White Chemists Olanzapine [TW]
			<sup>B</sup> 3.00	22.40	20.61	<sup>a</sup> Zyprexa [LY]	

■ OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5856**

Schizophrenia

**Authority required (STREAMLINED)****5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 10 mg tablet, 28**

1042W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.16	23.37	<sup>a</sup> Olanzapine genericealth 10 [GQ]

**olanzapine 10 mg tablet, 28**

8187X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.16	23.37	<sup>a</sup> APO-Olanzapine [TX] <sup>a</sup> Olanzacor 10 [CR] <sup>a</sup> Olanzapine-DRLA [RZ] <sup>a</sup> Olanzapine Sandoz [SZ] <sup>a</sup> PRYZEX [RW]  <sup>a</sup> Zypine [AF]	<sup>a</sup> Chem mart Olanzapine [CH] <sup>a</sup> Olanzapine AN [EA] <sup>a</sup> Olanzapine RBX [RA] <sup>a</sup> Ozin 10 [DO] <sup>a</sup> Terry White Chemists Olanzapine [TW]
			<sup>b</sup> 3.00	25.16	23.37	<sup>a</sup> Zyprexa [LY]	

**■ OLANZAPINE**

**Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5856**

Schizophrenia

**Authority required (STREAMLINED)****5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 5 mg wafer, 28**

8433W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.57	17.78	<sup>a</sup> Zypine ODT [AF]
			<sup>b</sup> 3.00	19.57	17.78	<sup>a</sup> Zyprexa Zydis [LY]

**OLANZAPINE Tablet 5 mg (orally disintegrating), 28**

3381Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.57	17.78	<sup>a</sup> APO-Olanzapine ODT [TX] <sup>a</sup> Olanzapine ODT-DRLA [RZ]  <sup>a</sup> Olanzapine Sandoz ODT 5 [SZ] <sup>a</sup> PRYZEX ODT [RW]	<sup>a</sup> Olanzapine AN ODT [EA] <sup>a</sup> Olanzapine ODT genericealth 5 [GQ] <sup>a</sup> Ozin ODT 5 [DO]

**■ OLANZAPINE**

**Note** Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5856**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 10 mg wafer, 28**

8434X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.16	23.37	<sup>a</sup> Zypine ODT [AF]
			<sup>B</sup> 3.00	25.16	23.37	<sup>a</sup> Zyprexa Zydis [LY]

**OLANZAPINE Tablet 10 mg (orally disintegrating), 28**

3382B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.16	23.37	<sup>a</sup> APO-Olanzapine ODT [TX]	<sup>a</sup> Olanzapine AN ODT [EA]
						<sup>a</sup> Olanzapine ODT-DRLA [RZ]	<sup>a</sup> Olanzapine ODT generichealth 10 [GQ]
						<sup>a</sup> Olanzapine Sandoz ODT 10 [SZ]	<sup>a</sup> Ozin ODT 10 [DO]
						<sup>a</sup> PRYZEX ODT [RW]	

▪ **OLANZAPINE**

**Note** Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5856**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 15 mg tablet, 28**

3384D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.70	28.91	<sup>a</sup> APO-Olanzapine ODT [TX]	<sup>a</sup> Olanzapine AN ODT [EA]
						<sup>a</sup> Olanzapine Sandoz ODT 15 [SZ]	<sup>a</sup> Ozin ODT 15 [DO]

**olanzapine 15 mg wafer, 28**

8952E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.70	28.91	<sup>a</sup> Zypine ODT [AF]
			<sup>B</sup> 3.00	30.70	28.91	<sup>a</sup> Zyprexa Zydis [LY]

▪ **OLANZAPINE**

**Note** Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5856**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 20 mg tablet, 28**

3385E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.24	34.45	<sup>a</sup> APO-Olanzapine ODT [TX]	<sup>a</sup> Olanzapine AN ODT [EA]
						<sup>a</sup> Olanzapine Sandoz ODT 20 [SZ]	<sup>a</sup> Ozin ODT 20 [DO]

**olanzapine 20 mg wafer, 28**

8953F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	33.24	34.45	<sup>a</sup> Zypine ODT [AF]
			<sup>b</sup> 3.00	36.24	34.45	<sup>a</sup> Zyprexa Zydis [LY]

**■ OLANZAPINE**

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

**Note** Special Pricing Arrangements apply.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4304**

Schizophrenia

**olanzapine 210 mg modified release injection [1 vial] (& inert substance diluent [3 mL vial], 1 pack**

9294E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*495.77	38.80	Zyprexa Relprevv [LY]

**olanzapine 300 mg modified release injection [1 vial] (& inert substance diluent [3 mL vial], 1 pack**

9295F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*803.77	38.80	Zyprexa Relprevv [LY]

**olanzapine 405 mg modified release injection [1 vial] (& inert substance diluent [3 mL vial], 1 pack**

9303P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	495.77	38.80	Zyprexa Relprevv [LY]

**■ QUETIAPINE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5611**

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)****5639**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**quetiapine 200 mg modified release tablet, 60**

9203J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	45.07	38.80	<sup>a</sup> APO-Quetiapine XR [TX]	<sup>a</sup> QUETIAPINE-AS XR [RW]
						<sup>a</sup> Seroquel XR [AP]	<sup>a</sup> Tevatiapine XR [TB]

**quetiapine 400 mg modified release tablet, 60**

9205L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	70.58	38.80	<sup>a</sup> APO-Quetiapine XR [TX]	<sup>a</sup> QUETIAPINE-AS XR [RW]
						<sup>a</sup> Seroquel XR [AP]	<sup>a</sup> Tevatiapine XR [TB]

**quetiapine 150 mg modified release tablet, 60**

5458G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.61	28.82	<sup>a</sup> QUEPINE XR [RW]	<sup>a</sup> Seroquel XR [AP]
						<sup>a</sup> Tevatiapine XR [TB]	

**quetiapine 300 mg modified release tablet, 60**

9204K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	54.73	38.80	<sup>a</sup> APO-Quetiapine XR [TX]	<sup>a</sup> QUETIAPINE-AS XR [RW]

<sup>a</sup> Seroquel XR [AP]

<sup>a</sup> Tevatiapine XR [TB]

**quetiapine 100 mg tablet, 90**

8457D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	27.61	28.82	<sup>a</sup> APO-Quetiapine [TX] <sup>a</sup> Delucon 100 [DO] <sup>a</sup> Pharmacor Quetiapine 100 [CR] <sup>a</sup> Quetiapine Actavis 100 [ED] <sup>a</sup> Quetiapine-DRLA [RZ] <sup>a</sup> Quetiapine RBX [RA] <sup>a</sup> Seroquel [AP] <sup>a</sup> Terry White Chemists Quetiapine [TW]	<sup>a</sup> Chem mart Quetiapine [CH] <sup>a</sup> Kaptan [ER] <sup>a</sup> Quetia 100 [RW] <sup>a</sup> Quetiapine AN [EA] <sup>a</sup> Quetiapine GH 100 [GQ] <sup>a</sup> Quetiapine Sandoz [SZ] <sup>a</sup> Syquet [AF]

**quetiapine 200 mg tablet, 60**

8458E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	33.59	34.80	<sup>a</sup> APO-Quetiapine [TX] <sup>a</sup> Delucon 200 [DO] <sup>a</sup> Pharmacor Quetiapine 200 [CR] <sup>a</sup> Quetiapine Actavis 200 [ED] <sup>a</sup> Quetiapine-DRLA [RZ] <sup>a</sup> Quetiapine RBX [RA] <sup>a</sup> Seroquel [AP] <sup>a</sup> Terry White Chemists Quetiapine [TW]	<sup>a</sup> Chem mart Quetiapine [CH] <sup>a</sup> Kaptan [ER] <sup>a</sup> Quetia 200 [RW] <sup>a</sup> Quetiapine AN [EA] <sup>a</sup> Quetiapine GH 200 [GQ] <sup>a</sup> Quetiapine Sandoz [SZ] <sup>a</sup> Syquet [AF]

**quetiapine 50 mg modified release tablet, 60**

9202H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.77	23.98	<sup>a</sup> APO-Quetiapine XR [TX] <sup>a</sup> Seroquel XR [AP]	<sup>a</sup> QUETIAPINE-AS XR [RW] <sup>a</sup> Tevatiapine XR [TB]

**quetiapine 300 mg tablet, 60**

8580N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	44.12	38.80	<sup>a</sup> APO-Quetiapine [TX] <sup>a</sup> Delucon 300 [DO] <sup>a</sup> Pharmacor Quetiapine 300 [CR] <sup>a</sup> Quetiapine Actavis 300 [ED] <sup>a</sup> Quetiapine-DRLA [RZ] <sup>a</sup> Quetiapine RBX [RA] <sup>a</sup> Seroquel [AP] <sup>a</sup> Terry White Chemists Quetiapine [TW]	<sup>a</sup> Chem mart Quetiapine [CH] <sup>a</sup> Kaptan [ER] <sup>a</sup> Quetia 300 [RW] <sup>a</sup> Quetiapine AN [EA] <sup>a</sup> Quetiapine GH 300 [GQ] <sup>a</sup> Quetiapine Sandoz [SZ] <sup>a</sup> Syquet [AF]

▪ **QUETIAPINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4391**

Schizophrenia

**Clinical criteria:**

- The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

**4396**

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

**4385**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- The treatment must be for dose titration purposes.

**quetiapine 25 mg tablet, 60**

8456C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	16.93	18.14	<sup>a</sup> APO-Quetiapine [TX] <sup>a</sup> Delucon 25 [DO] <sup>a</sup> Pharmacor Quetiapine 25 [CR] <sup>a</sup> Quetiapine AN [EA] <sup>a</sup> Quetiapine GH 25 [GQ] <sup>a</sup> Quetiapine Sandoz [SZ] <sup>a</sup> Syquet [AF]	<sup>a</sup> Chem mart Quetiapine [CH] <sup>a</sup> Kaptan [ER] <sup>a</sup> Quetia 25 [RW] <sup>a</sup> Quetiapine-DRLA [RZ] <sup>a</sup> Quetiapine RBX [RA] <sup>a</sup> Seroquel [AP] <sup>a</sup> Terry White Chemists Quetiapine [TW]

**Benzamides****■ AMISULPRIDE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**amisulpride 400 mg tablet, 60**

8596K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	65.46	38.80	<sup>a</sup> Amipride 400 [RW] <sup>a</sup> Amisulpride AN [EA] <sup>a</sup> APO-Amisulpride [TX] <sup>a</sup> Solian 400 [SW]	<sup>a</sup> Amisulpride 400 Winthrop [WA] <sup>a</sup> Amisulpride Sandoz [SZ] <sup>a</sup> Pharmacor Amisulpride [CR] <sup>a</sup> Sulprix [AF]

**amisulpride 100 mg/mL oral liquid, 60 mL**

8736T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*140.47	38.80	Solian Solution [SW]	

**amisulpride 200 mg tablet, 60**

8595J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	41.08	38.80	<sup>a</sup> Amisulpride 200 Winthrop [WA] <sup>a</sup> Amisulpride Sandoz [SZ] <sup>a</sup> Pharmacor Amisulpride [CR] <sup>a</sup> Sulprix [AF]	<sup>a</sup> Amisulpride AN [EA] <sup>a</sup> APO-Amisulpride [TX] <sup>a</sup> Solian 200 [SW]

**amisulpride 100 mg tablet, 30**

8594H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.05	19.26	<sup>a</sup> Amisulpride 100 Winthrop [WA] <sup>a</sup> Amisulpride Sandoz [SZ] <sup>a</sup> Pharmacor Amisulpride [CR] <sup>a</sup> Sulprix [AF]	<sup>a</sup> Amisulpride AN [EA] <sup>a</sup> APO-Amisulpride [TX] <sup>a</sup> Solian 100 [SW]

**Other antipsychotics****■ ARIPIPRAZOLE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**aripiprazole 400 mg injection: modified release [1 x 400 mg vial] (&) inert substance diluent [1 vial], 1 pack**

10219W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	373.70	38.80	Abilify Maintena [LU]	

**aripiprazole 15 mg tablet, 30**

8718W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	161.22	38.80	<sup>a</sup> Abilify [OS]	<sup>a</sup> Abyraz [AF]

<sup>a</sup> APO-Aripiprazole [TX]      <sup>a</sup> Aripiprazole AN [EA]  
<sup>a</sup> Aripiprazole GH [GQ]      <sup>a</sup> Aripiprazole Sandoz [SZ]  
<sup>a</sup> Tevaripiprazole [TB]

**aripiprazole 20 mg tablet, 30**

8719X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	193.94	38.80	<sup>a</sup> Abilify [OS] <sup>a</sup> APO-Aripiprazole [TX] <sup>a</sup> Aripiprazole GH [GQ] <sup>a</sup> Tevaripiprazole [TB]	<sup>a</sup> Abyraz [AF] <sup>a</sup> Aripiprazole AN [EA] <sup>a</sup> Aripiprazole Sandoz [SZ]

**aripiprazole 10 mg tablet, 30**

8717T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	116.89	38.80	<sup>a</sup> Abilify [OS] <sup>a</sup> APO-Aripiprazole [TX] <sup>a</sup> Aripiprazole GH [GQ] <sup>a</sup> Tevaripiprazole [TB]	<sup>a</sup> Abyraz [AF] <sup>a</sup> Aripiprazole AN [EA] <sup>a</sup> Aripiprazole Sandoz [SZ]

**aripiprazole 30 mg tablet, 30**

8720Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	235.28	38.80	<sup>a</sup> Abilify [OS] <sup>a</sup> APO-Aripiprazole [TX] <sup>a</sup> Aripiprazole GH [GQ] <sup>a</sup> Tevaripiprazole [TB]	<sup>a</sup> Abyraz [AF] <sup>a</sup> Aripiprazole AN [EA] <sup>a</sup> Aripiprazole Sandoz [SZ]

**aripiprazole 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 vial], 1 pack**

10224D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	299.91	38.80	Abilify Maintena [LU]

▪ **BREXPIPIRAZOLE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4246**  
Schizophrenia

**brexpiprazole 2 mg tablet, 30**

11188W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	142.37	38.80	Rexulti [LU]

**brexpiprazole 4 mg tablet, 30**

11184P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	142.37	38.80	Rexulti [LU]

**brexpiprazole 3 mg tablet, 30**

11190Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	142.37	38.80	Rexulti [LU]

**brexpiprazole 1 mg tablet, 30**

11189X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	142.37	38.80	Rexulti [LU]

▪ **PALIPERIDONE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4246**  
Schizophrenia

**paliperidone 3 mg modified release tablet, 28**

9140C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	74.29	38.80	Invega [JC]

**paliperidone 25 mg modified release injection, 1 syringe**

5100K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	134.77	38.80	Invega Sustenna [JC]

**paliperidone 9 mg modified release tablet, 28**

9142E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	203.00	38.80	Invega [JC]

**paliperidone 75 mg modified release injection, 1 syringe**

5103N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	337.84	38.80	Invega Sustenna [JC]

**paliperidone 6 mg modified release tablet, 28**

9141D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	138.77	38.80	Invega [JC]

**paliperidone 100 mg modified release injection, 1 syringe**

5107T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	414.09	38.80	Invega Sustenna [JC]

**paliperidone 50 mg modified release injection, 1 syringe**

5102M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	260.81	38.80	Invega Sustenna [JC]

**paliperidone 150 mg modified release injection, 1 syringe**

5109X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	414.09	38.80	Invega Sustenna [JC]

**■ PALIPERIDONE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)****6832**

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

**paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe**

11072R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	1003.94	38.80	Invega Trinza [JC]

**paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe**

11094X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	1219.20	38.80	Invega Trinza [JC]

**paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe**

11085K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	772.84	38.80	Invega Trinza [JC]

**paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe**

11066K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	1219.20	38.80	Invega Trinza [JC]

**■ RISPERIDONE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5907**

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

**risperidone 1 mg/mL oral liquid, 100 mL**

8100H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	112.55	38.80	Risperdal [JC]

**risperidone 2 mg tablet, 60**

3170W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.36	26.57	<sup>a</sup> APO-Risperidone [TX] <sup>a</sup> Rispa [RW] <sup>a</sup> Rispericor 2 [CR] <sup>a</sup> Risperidone generichealth [GQ] <sup>a</sup> Rispermia [ER]	<sup>a</sup> Ozidal [RA] <sup>a</sup> Risperdal [JC] <sup>a</sup> Risperidone AMNEAL [EF] <sup>a</sup> Risperidone Sandoz [SZ] <sup>a</sup> Rixadone [AF]

**risperidone 3 mg tablet, 60**

3171X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.09	34.30	<sup>a</sup> APO-Risperidone [TX] <sup>a</sup> Rispa [RW] <sup>a</sup> Risperidone AMNEAL [EF] <sup>a</sup> Risperidone Sandoz [SZ] <sup>a</sup> Rixadone [AF]	<sup>a</sup> Ozidal [RA] <sup>a</sup> Risperdal [JC] <sup>a</sup> Risperidone generichealth [GQ] <sup>a</sup> Rispermia [ER]

**risperidone 4 mg tablet, 60**

3172Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.79	38.80	<sup>a</sup> APO-Risperidone [TX] <sup>a</sup> Rispa [RW] <sup>a</sup> Risperidone AMNEAL [EF] <sup>a</sup> Risperidone Sandoz [SZ] <sup>a</sup> Rixadone [AF]	<sup>a</sup> Ozidal [RA] <sup>a</sup> Risperdal [JC] <sup>a</sup> Risperidone generichealth [GQ] <sup>a</sup> Rispermia [ER]

**risperidone 1 mg tablet, 60**

3169T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.33	18.54	<sup>a</sup> APO-Risperidone [TX] <sup>a</sup> Rispa [RW] <sup>a</sup> Rispericor 1 [CR] <sup>a</sup> Risperidone generichealth [GQ] <sup>a</sup> Rispermia [ER]	<sup>a</sup> Ozidal [RA] <sup>a</sup> Risperdal [JC] <sup>a</sup> Risperidone AMNEAL [EF] <sup>a</sup> Risperidone Sandoz [SZ] <sup>a</sup> Rixadone [AF]

**■ RISPERIDONE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6897**

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)****6938**

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 2 mg tablet, 60**

9079W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	25.36	26.57	<sup>a</sup> APO-Risperidone [TX] <sup>a</sup> Rispa [RW] <sup>a</sup> Rispericor 2 [CR] <sup>a</sup> Risperidone generichealth [GQ] <sup>a</sup> Rispermia [ER]	<sup>a</sup> Ozidal [RA] <sup>a</sup> Risperdal [JC] <sup>a</sup> Risperidone AMNEAL [EF] <sup>a</sup> Risperidone Sandoz [SZ] <sup>a</sup> Rixadone [AF]

**■ RISPERIDONE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5912**

Bipolar I disorder

**Clinical criteria:**

- The condition must be refractory to treatment, **AND**
- The treatment must be in combination with lithium or sodium valproate, **AND**
- The treatment must be maintenance therapy.

**risperidone 37.5 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

8781E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*345.33	38.80	Risperdal Consta [JC]

**risperidone 50 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

8782F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*423.51	38.80	Risperdal Consta [JC]

**risperidone 25 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

8780D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*266.31	38.80	Risperdal Consta [JC]

**■ RISPERIDONE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.**Authority required (STREAMLINED)****5903**

Schizophrenia

**risperidone 500 microgram tablet, 60**

8869T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.22	19.43	<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]

<sup>a</sup> Rispericor 0.5 [CR]                      <sup>a</sup> Risperidone AMNEAL [EF]  
<sup>a</sup> Risperidone Sandoz [SZ]                <sup>a</sup> Rispernia [ER]  
<sup>a</sup> Rixadone [AF]

**risperidone 500 microgram tablet, 20**

1846E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*18.22	19.43	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> Risperdal [JC]

■ **RISPERIDONE**

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5993**

Behavioural disturbances

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Authority required (STREAMLINED)**

**6897**

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

**6938**

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 1 mg/mL oral liquid, 100 mL**

9293D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	2	..	112.55	38.80	Risperdal [JC]

**risperidone 1 mg tablet, 60**

8789N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.33	18.54	<sup>a</sup> APO-Risperidone [TX] <sup>a</sup> Rispa [RW] <sup>a</sup> Rispericor 1 [CR] <sup>a</sup> Risperidone generichealth [GQ] <sup>a</sup> Rispernia [ER]	<sup>a</sup> Ozidal [RA] <sup>a</sup> Risperdal [JC] <sup>a</sup> Risperidone AMNEAL [EF] <sup>a</sup> Risperidone Sandoz [SZ] <sup>a</sup> Rixadone [AF]

## ▪ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**6010**

Behavioural disturbances

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Authority required (STREAMLINED)**

**6898**

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

**6899**

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

### risperidone 500 microgram tablet, 60

8787L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	18.22	19.43	<sup>a</sup> Ozidal [RA] <sup>a</sup> Rispericor 0.5 [CR] <sup>a</sup> Risperidone Sandoz [SZ] <sup>a</sup> Rixadone [AF]	<sup>a</sup> Rispa [RW] <sup>a</sup> Risperidone AMNEAL [EF] <sup>a</sup> Rispertia [ER]

### risperidone 500 microgram tablet, 20

1842Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	3	2	..	*18.22	19.43	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> Risperdal [JC]

## ANXIOLYTICS

### Benzodiazepine derivatives

## ▪ ALPRAZOLAM

**Note** Pharmaceutical benefits that have the form alprazolam tablet 1 mg are equivalent for the purposes of substitution.

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**alprazolam 1 mg tablet, 10**

11186R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.80	19.01	<sup>a</sup> Alprax 1 [QA]	<sup>a</sup> Kalma 1 [AF]

**alprazolam 1 mg tablet, 50**

2132F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	0.2	..	..	*22.79	24.00	<sup>a</sup> Alprax 1 [QA]	<sup>a</sup> Kalma 1 [AF]

**ALPRAZOLAM**

**Note** Pharmaceutical benefits that have the form alprazolam tablet 500 micrograms are equivalent for the purposes of substitution.

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**alprazolam 500 microgram tablet, 10**

11187T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.74	17.95	<sup>a</sup> Alprax 0.5 [QA]	<sup>a</sup> Kalma 0.5 [AF]

**alprazolam 500 microgram tablet, 50**

2131E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	0.2	..	..	*21.10	22.31	<sup>a</sup> Alprax 0.5 [QA]	<sup>a</sup> Kalma 0.5 [AF]

**ALPRAZOLAM**

**Note** Pharmaceutical benefits that have the form alprazolam tablet 250 micrograms are equivalent for the purposes of substitution.

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**alprazolam 250 microgram tablet, 10**

11205R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.73	16.94	<sup>a</sup> Kalma 0.25 [AF]	

**alprazolam 250 microgram tablet, 50**

2130D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	0.2	..	..	*19.49	20.70	<sup>a</sup> Alprax 0.25 [QA]	<sup>a</sup> Kalma 0.25 [AF]

**DIAZEPAM****diazepam 2 mg tablet, 50**

5071X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.41	13.62	<sup>a</sup> APO-Diazepam [TX]	<sup>a</sup> Valpam 2 [RW]
			<sup>b</sup> 2.99	15.40	13.62	<sup>a</sup> Antenex 2 [AF]	

**diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules**

5073B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.11	18.32	Hospira Pty Limited [PF]	

**diazepam 5 mg tablet, 50**

5072Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.48	13.69	<sup>a</sup> Antenex 5 [AF]	<sup>a</sup> APO-Diazepam [TX]
						<sup>a</sup> Ranzepam [RA]	<sup>a</sup> Valpam 5 [RW]
			<sup>b</sup> 2.19	14.67	13.69	<sup>a</sup> Valium [RO]	

**DIAZEPAM****Authority required**

Chronic spasticity

**Population criteria:**

- Patient must be under 18 years of age.

**diazepam 1 mg/mL oral liquid, 100 mL**

2669L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	42.95	38.80	Diazepam Elixir [ON]

**■ DIAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

- the treatment of disabling spasticity; or
- malignant neoplasia (late stage); or
- use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
- use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

**diazepam 2 mg tablet, 50**

3161J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.41	13.62	<sup>a</sup> APO-Diazepam [TX]	<sup>a</sup> Valpam 2 [RW]
			<sup>b</sup> 2.99	15.40	13.62	<sup>a</sup> Antenex 2 [AF]	

**diazepam 5 mg tablet, 50**

3162K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.48	13.69	<sup>a</sup> Antenex 5 [AF]	<sup>a</sup> APO-Diazepam [TX]
						<sup>a</sup> Ranzepam [RA]	<sup>a</sup> Valpam 5 [RW]
			<sup>b</sup> 2.19	14.67	13.69	<sup>a</sup> Valium [RO]	

**■ DIAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

- the treatment of disabling spasticity; or
- malignant neoplasia (late stage); or
- use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
- use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

**Note** Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

**diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules**

2558P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	17.11	18.32	Hospira Pty Limited [PF]

**■ OXAZEPAM****oxazepam 15 mg tablet, 25**

5192G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	12.51	13.72	<sup>a</sup> Alepam 15 [AF]
			<sup>b</sup> 2.66	15.17	13.72	<sup>a</sup> Serepax [QA]

**oxazepam 30 mg tablet, 25**

5193H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.17	13.38	<sup>a</sup> Alepam 30 [AF]	<sup>a</sup> APO-Oxazepam [TX]
						<sup>a</sup> Murelax [RW]	
			<sup>b</sup> 2.33	14.50	13.38	<sup>a</sup> Serepax [QA]	

**■ OXAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam below.

**oxazepam 15 mg tablet, 25**

3132W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	12.51	13.72	<sup>a</sup> Alepam 15 [AF]
			<sup>b</sup> 2.66	15.17	13.72	<sup>a</sup> Serepax [QA]

**oxazepam 30 mg tablet, 25**

3133X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.17	13.38	<sup>a</sup> Alepam 30 [AF]	<sup>a</sup> APO-Oxazepam [TX]
						<sup>a</sup> Murelax [RW]	
			<sup>B</sup> 2.33	14.50	13.38	<sup>a</sup> Serepax [QA]	

■ **OXAZEPAM**

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**oxazepam 15 mg tablet, 25**

3134Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*13.93	15.14	<sup>a</sup> Alepam 15 [AF]	
						<sup>a</sup> Serepax [QA]	
			<sup>B</sup> 5.32	*19.25	15.14		

**oxazepam 30 mg tablet, 25**

3135B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*13.25	14.46	<sup>a</sup> Alepam 30 [AF]	<sup>a</sup> APO-Oxazepam [TX]
						<sup>a</sup> Murelax [RW]	
			<sup>B</sup> 4.66	*17.91	14.46	<sup>a</sup> Serepax [QA]	

**HYPNOTICS AND SEDATIVES**

*Benzodiazepine derivatives*

■ **NITRAZEPAM**

**nitrazepam 5 mg tablet, 25**

5189D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.70	13.91	<sup>a</sup> Alodorm [AF]	
						<sup>a</sup> Mogadon [IA]	
			<sup>B</sup> 1.24	13.94	13.91		

■ **NITRAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam below.

**nitrazepam 5 mg tablet, 25**

2723H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.70	13.91	<sup>a</sup> Alodorm [AF]	
						<sup>a</sup> Mogadon [IA]	
			<sup>B</sup> 1.24	13.94	13.91		

■ **NITRAZEPAM**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

2732T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*14.31	15.52	<sup>a</sup> Alodorm [AF]
			<sup>B</sup> 2.48	*16.79	15.52	<sup>a</sup> Mogadon [IA]

**■ TEMAZEPAM****temazepam 10 mg tablet, 25**

5221T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.17	13.38	<sup>a</sup> APO-Temazepam [TX]	<sup>a</sup> Temaze [AF]
						<sup>a</sup> Temtabs [FM]	
			<sup>B</sup> 3.48	15.65	13.38	<sup>a</sup> Normison [QA]	

**■ TEMAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

**temazepam 10 mg tablet, 25**

2089Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.17	13.38	<sup>a</sup> APO-Temazepam [TX]	<sup>a</sup> Temaze [AF]
						<sup>a</sup> Temtabs [FM]	
			<sup>B</sup> 3.48	15.65	13.38	<sup>a</sup> Normison [QA]	

**■ TEMAZEPAM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**temazepam 10 mg tablet, 25**

2088X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*13.25	14.46	<sup>a</sup> APO-Temazepam [TX]	<sup>a</sup> Temaze [AF]
						<sup>a</sup> Temtabs [FM]	
			<sup>B</sup> 6.96	*20.21	14.46	<sup>a</sup> Normison [QA]	

■ **PSYCHOANALEPTICS**

**ANTIDEPRESSANTS**

*Non-selective monoamine reuptake inhibitors*

■ **AMITRIPTYLINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**amitriptyline hydrochloride 25 mg tablet, 50**

2418G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	13.79	15.00	<sup>a</sup> Amitriptyline Alphapharm 25 [AL]	<sup>a</sup> APO-Amitriptyline 25 [TX]
						<sup>a</sup> Chem mart Amitriptyline [CH]	<sup>a</sup> ENTRIP [RW]
						<sup>a</sup> Terry White Chemists Amitriptyline [TW]	
			<sup>B</sup> 1.96	15.75	15.00	<sup>a</sup> Endep 25 [AF]	

**amitriptyline hydrochloride 10 mg tablet, 50**

2417F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	13.60	14.81	<sup>a</sup> Amitriptyline Alphapharm 10 [AL]	<sup>a</sup> APO-Amitriptyline 10 [TX]
						<sup>a</sup> Chem mart Amitriptyline [CH]	<sup>a</sup> ENTRIP [RW]
						<sup>a</sup> Terry White Chemists Amitriptyline [TW]	
			<sup>B</sup> 1.95	15.55	14.81	<sup>a</sup> Endep 10 [AF]	

**amitriptyline hydrochloride 50 mg tablet, 50**

2429W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	14.19	15.40	<sup>a</sup> Amitriptyline Alphapharm 50 [AL]	<sup>a</sup> APO-Amitriptyline 50 [TX]
						<sup>a</sup> Chem mart Amitriptyline [CH]	<sup>a</sup> ENTRIP [RW]
						<sup>a</sup> Terry White Chemists Amitriptyline [TW]	
			<sup>B</sup> 1.95	16.14	15.40	<sup>a</sup> Endep 50 [AF]	

■ **CLOMIPRAMINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Cataplexy

**Clinical criteria:**

- The condition must be associated with narcolepsy.

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Phobic disorders

**Population criteria:**

- Patient must be an adult.

**clomipramine hydrochloride 25 mg tablet, 50**

1561E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.03	18.24	<sup>a</sup> GenRx Clomipramine [GX]	<sup>a</sup> Placil [AF]
						<sup>a</sup> Anafranil 25 [SZ]	
				<sup>B</sup> 4.41	21.44	18.24	

■ **DOTHIEPIN**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**dothiepin hydrochloride 75 mg tablet, 30**

1358L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	13.66	14.87	Dothep 75 [AF]

**dothiepin hydrochloride 25 mg capsule, 50**

1357K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	13.66	14.87	Dothep 25 [AF]

**■ DOXEPIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**doxepin 10 mg capsule, 50**

1011F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	13.98	15.19	Deptran 10 [AF]
			<sup>B</sup> 7.00	20.98	15.19	Sinequan [PF]

**doxepin 50 mg tablet, 50**

1012G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	14.89	16.10	Deptran 50 [AF]

**doxepin 25 mg capsule, 50**

1013H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	14.09	15.30	Deptran 25 [AF]
			<sup>B</sup> 7.00	21.09	15.30	Sinequan [PF]

**■ IMIPRAMINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**imipramine hydrochloride 10 mg tablet, 50**

2420J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	15.36	16.57	Tofranil 10 [GH]

**imipramine hydrochloride 25 mg tablet, 50**

2421K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18.73	19.94	Tofranil 25 [GH]

**■ NORTRIPTYLINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depression

**Clinical criteria:**

- The treatment must be for use when other anti-depressant therapy has failed.

**Restricted benefit**

Major depression

**Clinical criteria:**

- The treatment must be for use when other anti-depressant therapy is contraindicated.

**nortriptyline 25 mg tablet, 50**

2523T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.11	18.32	<sup>a</sup> Allegron [RW]	<sup>a</sup> NortriTABS 25 mg [GH]

**nortriptyline 10 mg tablet, 50**

2522R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.87	17.08	<sup>a</sup> Allegron [RW]	<sup>a</sup> NortriTABS 10 mg [GH]

**Selective serotonin reuptake inhibitors****■ CITALOPRAM****Restricted benefit**

Major depressive disorders

**citalopram 10 mg tablet, 28**

8702B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.06	13.27	<sup>a</sup> Celapram [AF] <sup>a</sup> Citalopram AN [EF]	<sup>a</sup> Citalopram Actavis [EA] <sup>a</sup> Talam [RW]

**citalopram 40 mg tablet, 28**

8703C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.28	14.49	<sup>a</sup> APO-Citalopram [TX] <sup>a</sup> Celapram [AF] <sup>a</sup> Citalopram AN [EA] <sup>a</sup> Talam [RW]	<sup>a</sup> Auro-Citalopram 40 [DO] <sup>a</sup> Citalopram Actavis [ED] <sup>a</sup> Citalopram Sandoz [SZ]

**citalopram 20 mg tablet, 28**

8220P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.39	13.60	<sup>a</sup> APO-Citalopram [TX] <sup>a</sup> Celapram [AF] <sup>a</sup> Chem mart Citalopram [CH] <sup>a</sup> Citalopram AN [EA] <sup>a</sup> Pharmacor Citalo 20 [CR] <sup>a</sup> Terry White Chemists Citalopram [TW] <sup>a</sup> Cipramil [LU]	<sup>a</sup> Auro-Citalopram 20 [DO] <sup>a</sup> Celica [RA] <sup>a</sup> Citalopram Actavis [ED] <sup>a</sup> Citalopram Sandoz [SZ] <sup>a</sup> Talam [RW]
			<sup>b</sup> 7.46	19.85	13.60		

▪ **ESCITALOPRAM**

**Restricted benefit**

Major depressive disorders

**escitalopram 10 mg tablet, 28**

8700X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.19	14.40	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Chem mart Escitalopram [CH] <sup>a</sup> Escicor 10 [RA] <sup>a</sup> Escitalopram-DRLA [RZ] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Esitalo [SZ] <sup>a</sup> LoxaLate [AF] <sup>a</sup> Terry White Chemists Escitalopram [TW] <sup>a</sup> Lexapro [LU]	<sup>a</sup> Blooms the Chemist Escitalopram [IB] <sup>a</sup> Cilopam-S [ER] <sup>a</sup> Escitalopram AN [EA] <sup>a</sup> Escitalopram generichealth [GQ] <sup>a</sup> Esipram [CF] <sup>a</sup> Lexam 10 [RW] <sup>a</sup> Pharmacor Escitalopram 10 [CR]
			<sup>b</sup> 8.49	21.68	14.40		

**escitalopram 20 mg tablet, 28**

8701Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.21	14.42	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Chem mart Escitalopram [CH] <sup>a</sup> Escicor 20 [RA] <sup>a</sup> Escitalopram-DRLA [RZ] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Esitalo [SZ] <sup>a</sup> LoxaLate [AF] <sup>a</sup> Terry White Chemists Escitalopram [TW] <sup>a</sup> Lexapro [LU]	<sup>a</sup> Blooms the Chemist Escitalopram [IB] <sup>a</sup> Cilopam-S [ER] <sup>a</sup> Escitalopram AN [EA] <sup>a</sup> Escitalopram generichealth [GQ] <sup>a</sup> Esipram [CF] <sup>a</sup> Lexam 20 [RW] <sup>a</sup> Pharmacor Escitalopram 20 [CR]
			<sup>b</sup> 8.84	22.05	14.42		

▪ **ESCITALOPRAM**

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 10 mg tablet, 28**

9432K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	13.19	14.40	<sup>a</sup> Esipram [CF]
			<sup>B</sup> 8.49	21.68	14.40	<sup>a</sup> Lexapro [LU]

**escitalopram 20 mg tablet, 28**

9433L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	13.21	14.42	<sup>a</sup> Esipram [CF]
			<sup>B</sup> 8.84	22.05	14.42	<sup>a</sup> Lexapro [LU]

**■ ESCITALOPRAM****Restricted benefit**

Major depressive disorders

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

# NERVOUS SYSTEM

General

## escitalopram 20 mg/mL oral liquid, 15 mL

10181W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	37.06	38.27	Lexapro [LU]

## FLUOXETINE

### Restricted benefit

Major depressive disorders

### Restricted benefit

Obsessive-compulsive disorder

## fluoxetine 20 mg dispersible tablet, 28

8270G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.80	16.01	<sup>a</sup> Lovan 20 Tab [AL]	<sup>a</sup> Zactin Tablet [AF]
			<sup>B</sup> 1.18	15.98	16.01	<sup>a</sup> Prozac Tab [LY]	

## fluoxetine 20 mg capsule, 28

1434L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.80	16.01	<sup>a</sup> APO-Fluoxetine [TX] <sup>a</sup> Blooms the Chemist Fluoxetine [IB] <sup>a</sup> FLUOTEX [RF] <sup>a</sup> Fluoxetine-GA [ED] <sup>a</sup> Fluoxetine Sandoz [SZ] <sup>a</sup> Lovan [AL]	<sup>a</sup> Auscap Aspen [RW] <sup>a</sup> Chem mart Fluoxetine [CH] <sup>a</sup> Fluoxetine AN [EA] <sup>a</sup> Fluoxetine generichealth [GQ] <sup>a</sup> GenRx Fluoxetine [GX] <sup>a</sup> Terry White Chemists Fluoxetine [TW]
			<sup>B</sup> 1.18	15.98	16.01	<sup>a</sup> Zactin [AF] <sup>a</sup> Prozac 20 [LY]	

## FLUVOXAMINE

### Restricted benefit

Major depressive disorders

### Restricted benefit

Obsessive-compulsive disorder

## fluvoxamine maleate 100 mg tablet, 30

8174F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.66	20.87	<sup>a</sup> APO-Fluvoxamine [TX] <sup>a</sup> Fluvoxamine AN [ED] <sup>a</sup> Movox 100 [AF]	<sup>a</sup> Faverin 100 [RW] <sup>a</sup> Fluvoxamine GA [EA] <sup>a</sup> Voxam [SZ]
			<sup>B</sup> 3.07	22.73	20.87	<sup>a</sup> Luvox [GO]	

## fluvoxamine maleate 50 mg tablet, 30

8512B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.75	17.96	<sup>a</sup> APO-Fluvoxamine [TX] <sup>a</sup> Fluvoxamine AN [ED] <sup>a</sup> Movox 50 [AL]	<sup>a</sup> Faverin 50 [RW] <sup>a</sup> Fluvoxamine GA [EA] <sup>a</sup> Voxam [SZ]
			<sup>B</sup> 3.08	19.83	17.96	<sup>a</sup> Luvox [GO]	

## PAROXETINE

### Restricted benefit

Major depressive disorders

### Restricted benefit

Obsessive-compulsive disorder

### Restricted benefit

Panic disorder

## paroxetine 20 mg tablet, 30

2242B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.51	15.72	<sup>a</sup> APO-Paroxetine [TX] <sup>a</sup> Extine 20 [RW] <sup>a</sup> Paroxetine AN [EA] <sup>a</sup> Paroxetine Sandoz [SZ] <sup>a</sup> Roxet 20 [DO]	<sup>a</sup> Chem mart Paroxetine [CH] <sup>a</sup> GenRx Paroxetine [GX] <sup>a</sup> Paroxetine GH [GQ] <sup>a</sup> Paxtine [AF] <sup>a</sup> Terry White Chemists Paroxetine [TW]
			<sup>B</sup> 2.58	17.09	15.72	<sup>a</sup> Aropax [AS]	

## SERTRALINE

### Restricted benefit

Major depressive disorders

**sertraline 100 mg tablet, 30**

2237R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.78	13.99	<sup>a</sup> APO-Sertraline [TX] <sup>a</sup> Chem mart Sertraline [CH] <sup>a</sup> Sertra 100 [RW] <sup>a</sup> Sertraline AN [EA] <sup>a</sup> Sertraline Sandoz [SZ] <sup>a</sup> Terry White Chemists Sertraline [TW]	<sup>a</sup> Auro-Sertraline 100 [DO] <sup>a</sup> Eleva 100 [AF] <sup>a</sup> Sertracor 100 [CR] <sup>a</sup> Sertraline generichealth [GQ] <sup>a</sup> Setrona [RA]
			<sup>b</sup> 5.80	18.58	13.99	<sup>a</sup> Zoloft [PF]	

**sertraline 50 mg tablet, 30**

2236Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.78	13.99	<sup>a</sup> APO-Sertraline [TX] <sup>a</sup> Chem mart Sertraline [CH] <sup>a</sup> Sertra 50 [RW] <sup>a</sup> Sertraline AN [EA] <sup>a</sup> Sertraline Sandoz [SZ] <sup>a</sup> Terry White Chemists Sertraline [TW]	<sup>a</sup> Auro-Sertraline 50 [DO] <sup>a</sup> Eleva 50 [AF] <sup>a</sup> Sertracor 50 [CR] <sup>a</sup> Sertraline generichealth [GQ] <sup>a</sup> Setrona [RA]
			<sup>b</sup> 5.80	18.58	13.99	<sup>a</sup> Zoloft [PF]	

**■ SERTRALINE****Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**sertraline 100 mg tablet, 30**

8837D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.78	13.99	<sup>a</sup> Auro-Sertraline 100 [DO] <sup>a</sup> Sertraline AN [EA]	<sup>a</sup> Eleva 100 [AF]
			<sup>b</sup> 5.80	18.58	13.99	<sup>a</sup> Zoloft [PF]	

**sertraline 50 mg tablet, 30**

8836C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	12.78	13.99	<sup>a</sup> Auro-Sertraline 50 [DO] <sup>a</sup> Sertraline AN [EA]	<sup>a</sup> Eleva 50 [AF]
			<sup>b</sup> 5.80	18.58	13.99	<sup>a</sup> Zoloft [PF]	

**Monoamine oxidase inhibitors, non-selective****■ PHENELZINE****Caution** This drug is an irreversible monoamine oxidase inhibitor.**Restricted benefit**

Depression

**Clinical criteria:**

- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

**phenelzine 15 mg tablet, 100**

2856H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	91.99	38.80	Nardil [LM]

**■ TRANYLCPROMINE****Caution** This drug is an irreversible monoamine oxidase inhibitor.**tranylcypromine 10 mg tablet, 50**

2444P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	55.92	38.80	Parnate [GH]

**Monoamine oxidase A inhibitors****■ MOCLOBEMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**moclobemide 300 mg tablet, 60**

8003F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.36	28.57	<sup>a</sup> Amira 300 [AF] <sup>a</sup> GenRx Moclobemide [GX] <sup>a</sup> Moclobemide Sandoz [SZ]	<sup>a</sup> Clobemix [ED] <sup>a</sup> Moclobemide AN [EA]
			<sup>B</sup> 3.00	30.36	28.57	<sup>a</sup> Aurorix 300 mg [HM]	

**moclobemide 150 mg tablet, 60**

1900B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.83	22.04	<sup>a</sup> Amira 150 [AF] <sup>a</sup> GenRx Moclobemide [GX] <sup>a</sup> Moclobemide Sandoz [SZ]	<sup>a</sup> Clobemix [ED] <sup>a</sup> Moclobemide AN [EA] <sup>a</sup> Mohexal [HX]
			<sup>B</sup> 3.00	23.83	22.04	<sup>a</sup> Aurorix [HM]	

*Other antidepressants*

▪ **DESVENLAFAXINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**Restricted benefit**

Major depressive disorders

**desvenlafaxine 50 mg modified release tablet, 28**

10234P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.36	26.57	<sup>a</sup> APO-Desvenlafaxine MR [TX]	<sup>a</sup> Desvenlafaxine GH XR [GQ]

**desvenlafaxine 50 mg modified release tablet, 28**

10241B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.36	26.57	<sup>a</sup> Desfax [AF] <sup>a</sup> Desvenlafaxine Actavis [EA]	<sup>a</sup> DESVEN [RW] <sup>a</sup> Desvenlafaxine Sandoz [SZ]

**desvenlafaxine 50 mg modified release tablet, 28**

9366Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	25.36	26.57	<sup>a</sup> Pristiq [PF]

**desvenlafaxine 100 mg modified release tablet, 28**

10231L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.61	29.82	<sup>a</sup> Desfax [AF] <sup>a</sup> Desvenlafaxine Actavis [EA]	<sup>a</sup> DESVEN [RW] <sup>a</sup> Desvenlafaxine Sandoz [SZ]

**desvenlafaxine 100 mg modified release tablet, 28**

10245F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.61	29.82	<sup>a</sup> APO-Desvenlafaxine MR [TX]	<sup>a</sup> Desvenlafaxine GH XR [GQ]

**desvenlafaxine 100 mg modified release tablet, 28**

9367B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	28.61	29.82	<sup>a</sup> Pristiq [PF]

▪ **DULOXETINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**duloxetine 30 mg enteric capsule, 28**

9155W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.24	16.45	<sup>a</sup> Andepra [EL] <sup>a</sup> Chem mart Duloxetine [CH] <sup>a</sup> Duloxetine AN [EA] <sup>a</sup> DYTREX 30 [RW] <sup>a</sup> Terry White Chemists Duloxetine [TW]	<sup>a</sup> APO-Duloxetine [TX] <sup>a</sup> Depreta 30 [DO] <sup>a</sup> Duloxetine GH [GQ] <sup>a</sup> Pharmacor Duloxetine 30 [CR] <sup>a</sup> Tixel [AL]
			<sup>B</sup> 1.90	17.14	16.45	<sup>a</sup> Cymbalta [LY]	

**duloxetine 60 mg enteric capsule, 28**

9156X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.01	18.22	<sup>a</sup> Andepra [EL] <sup>a</sup> Chem mart Duloxetine [CH] <sup>a</sup> Duloxetine AN [EA] <sup>a</sup> DYTREX 60 [RW] <sup>a</sup> Terry White Chemists Duloxetine [TW]	<sup>a</sup> APO-Duloxetine [TX] <sup>a</sup> Depreta 60 [DO] <sup>a</sup> Duloxetine GH [GQ] <sup>a</sup> Pharmacor Duloxetine 60 [CR] <sup>a</sup> Tixel [AL]
			<sup>B</sup> 1.91	18.92	18.22	<sup>a</sup> Cymbalta [LY]	

**■ LITHIUM CARBONATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**lithium carbonate 450 mg modified release tablet, 100**

8290H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*35.57	36.78	Quilonum SR [AS]

**lithium carbonate 250 mg tablet, 200**

3059B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	23.19	24.40	Lithicarb [AS]

**■ MIANSERIN**

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Severe depression

**mianserin hydrochloride 20 mg tablet, 50**

1628Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.54	28.75	Lumin 20 [AF]

**mianserin hydrochloride 10 mg tablet, 50**

1627P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.89	20.10	Lumin 10 [AF]

**■ MIRTAZAPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30**

8855C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.23	16.44	<sup>a</sup> Milivin OD 15 [DO] <sup>a</sup> Mirtazapine Sandoz ODT 15 [SZ]	<sup>a</sup> Mirtazapine AN ODT [EA]
			<sup>B</sup> 4.75	19.98	16.44	<sup>a</sup> Avanza SolTab [MK]	<sup>a</sup> Remeron SolTab [AF]

**mirtazapine 30 mg tablet, 30**

8513C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	14.69	15.90	<sup>a</sup> APO-Mirtazapine [TX] <sup>a</sup> Axit 30 [AF] <sup>a</sup> MIRTANZA [RF] <sup>a</sup> Mirtazapine GH [GQ] <sup>a</sup> Mirtazon [RW]	<sup>a</sup> Aurozapine 30 [DO] <sup>a</sup> Chem mart Mirtazapine [CH] <sup>a</sup> Mirtazapine AN [EA] <sup>a</sup> Mirtazapine Sandoz [SZ] <sup>a</sup> Terry White Chemists Mirtazapine [TW]
			<sup>B</sup> 4.20	18.89	15.90	<sup>a</sup> Avanza [MK]	

**mirtazapine 45 mg tablet, 30**

8883M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.09	18.30	<sup>a</sup> APO-Mirtazapine [TX] <sup>a</sup> Axit 45 [AF] <sup>a</sup> MIRTANZA [RF] <sup>a</sup> Mirtazapine GH [GQ] <sup>a</sup> Mirtazon [RW]	<sup>a</sup> Aurozapine 45 [DO] <sup>a</sup> Chem mart Mirtazapine [CH] <sup>a</sup> Mirtazapine AN [EA] <sup>a</sup> Mirtazapine Sandoz [SZ] <sup>a</sup> Terry White Chemists Mirtazapine [TW]

**mirtazapine 15 mg tablet, 30**

9365X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	13.49	14.70	<sup>a</sup> APO-Mirtazapine [TX] <sup>a</sup> MIRTANZA [RF]	<sup>a</sup> Axit 15 [AF] <sup>a</sup> Mirtazapine AN [EA]

**MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30**

8856D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.61	17.82	<sup>a</sup> Milivin OD 30 [DO] <sup>a</sup> Mirtazapine Sandoz ODT 30 [SZ]	<sup>a</sup> Mirtazapine AN ODT [EA]
			<sup>B</sup> 4.75	21.36	17.82	<sup>a</sup> Avanza SolTab [MK]	<sup>a</sup> Remeron SolTab [AF]

**MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30**

8857E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.39	20.60	<sup>a</sup> Milivin OD 45 [DO] <sup>a</sup> Mirtazapine Sandoz ODT 45 [SZ]	<sup>a</sup> Mirtazapine AN ODT [EA]
			<sup>B</sup> 4.75	24.14	20.60	<sup>a</sup> Avanza SolTab [MK]	<sup>a</sup> Remeron SolTab [AF]

▪ **REBOXETINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**reboxetine 4 mg tablet, 60**

8583R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	37.80	38.80	Edronax [PF]

▪ **VENLAFAXINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**venlafaxine 37.5 mg modified release capsule, 28**

8868R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	13.48	14.69	<sup>a</sup> Efexor-XR [PF] <sup>a</sup> Venlafaxine AN SR [EA]	<sup>a</sup> Elaxine SR 37.5 [ZP]

**venlafaxine 150 mg modified release capsule, 28**

8302Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	15.48	16.69	<sup>a</sup> APO-Venlafaxine XR [TX] <sup>a</sup> Chem mart Venlafaxine XR [CH]	<sup>a</sup> Blooms the Chemist Venlafaxine XR [IB] <sup>a</sup> Efexor-XR [PF]

<sup>a</sup> Elaxine SR 150 [ZP]	<sup>a</sup> Enlafax-XR [AF]
<sup>a</sup> Sandoz Venlafaxine XR [HX]	<sup>a</sup> Terry White Chemists Venlafaxine XR [TW]
<sup>a</sup> Venlafaxine AN SR [EA]	<sup>a</sup> Venlafaxine generichealth XR [GQ]
<sup>a</sup> Venlafaxine Sandoz XR [SZ]	<sup>a</sup> Venla RBX [RA]

**venlafaxine 75 mg modified release capsule, 28**

8301X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.69	15.90	<sup>a</sup> APO-Venlafaxine XR [TX]	<sup>a</sup> Blooms the Chemist Venlafaxine XR [IB]
						<sup>a</sup> Chem mart Venlafaxine XR [CH]	<sup>a</sup> Eflexor-XR [PF]
						<sup>a</sup> Elaxine SR 75 [ZP]	<sup>a</sup> Enlafax-XR [AF]
						<sup>a</sup> Sandoz Venlafaxine XR [HX]	<sup>a</sup> Terry White Chemists Venlafaxine XR [TW]
						<sup>a</sup> Venlafaxine AN SR [EA]	<sup>a</sup> Venlafaxine generichealth XR [GQ]
						<sup>a</sup> Venlafaxine Sandoz XR [SZ]	

**PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS***Centrally acting sympathomimetics***ARMODAFINIL**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulphate or modafinil.

**Authority required**

Narcolepsy

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**

- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

- a psychiatric disorder;
- a cardiovascular disorder;
- a history of substance abuse;
- glaucoma;
- any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

- a completed authority prescription form; and
- a completed Narcolepsy Initial PBS authority application and Supporting information form; and
- details of the contraindication or intolerance to dexamphetamine sulfate; and
- either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Authority required**

Narcolepsy

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**armodafinil 150 mg tablet, 30**

10912H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	153.34	38.80	Nuvigil [TB]

**armodafinil 50 mg tablet, 30**

10922W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*105.93	38.80	Nuvigil [TB]

**armodafinil 250 mg tablet, 30**

10919Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	250.17	38.80	Nuvigil [TB]

▪ **ATOMOXETINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**4578**

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**Authority required (STREAMLINED)**

**6279**

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamphetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**atomoxetine 10 mg capsule, 28**

9092M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*168.11	38.80	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

▪ **ATOMOXETINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6279**

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamphetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Authority required (STREAMLINED)****4578**

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**atomoxetine 18 mg capsule, 28**

9093N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*168.11	38.80	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 100 mg capsule, 28**

9290Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	113.15	38.80	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 60 mg capsule, 28**

9096R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*168.11	38.80	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 25 mg capsule, 28**

9094P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*168.11	38.80	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 80 mg capsule, 28**

9289X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	113.15	38.80	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 40 mg capsule, 28**

9095Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*168.11	38.80	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**■ DEXAMFETAMINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

**Authority required**

Narcolepsy

**dexamfetamine sulfate 5 mg tablet, 100**

1165H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	21.58	22.79	Aspen Pharma Pty Ltd [QA]

**■ LISDEXAMFETAMINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must require continuous coverage over 12 hours.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**lisdexamfetamine dimesilate 50 mg capsule, 30**

10474G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	117.10	38.80	Vyvanse [ZI]

**lisdexamfetamine dimesilate 70 mg capsule, 30**

10492F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	117.10	38.80	Vyvanse [ZI]

**lisdexamfetamine dimesilate 30 mg capsule, 30**

10486X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	117.10	38.80	Vyvanse [ZI]

▪ **METHYLPHENIDATE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours.

**methylphenidate hydrochloride 18 mg modified release tablet, 30**

2387P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	51.79	38.80	Concerta [JC]

**methylphenidate hydrochloride 27 mg modified release tablet, 30**

2172H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.93	38.80	Concerta [JC]

**methylphenidate hydrochloride 36 mg modified release tablet, 30**

2388Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.06	38.80	Concerta [JC]

**methylphenidate hydrochloride 54 mg modified release tablet, 30**

2432B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	69.21	38.80	Concerta [JC]

▪ **METHYLPHENIDATE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours.

**methylphenidate hydrochloride 40 mg modified release capsule, 30**

2283E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.03	38.80	Ritalin LA [NV]

**methylphenidate hydrochloride 20 mg modified release capsule, 30**

2276T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	45.04	38.80	Ritalin LA [NV]

**methylphenidate hydrochloride 30 mg modified release capsule, 30**

2280B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.50	38.80	Ritalin LA [NV]

**methylphenidate hydrochloride 10 mg modified release capsule, 30**

3440C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	35.77	36.98	Ritalin LA [NV]

**■ METHYLPHENIDATE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

**methylphenidate hydrochloride 10 mg tablet, 100**

8839F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.24	24.45	<sup>a</sup> Artige [NM]	<sup>a</sup> Ritalin 10 [NV]

**■ MODAFINIL**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulphate or armodafinil.

**Authority required**

Narcolepsy

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

- (a) a completed authority prescription form; and
  - (b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
  - (c) details of the contraindication or intolerance to dexamphetamine sulfate; and
  - (d) either:
    - (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
    - (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.
- The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Authority required**

Narcolepsy

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**modafinil 100 mg tablet, 60**

8816B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*285.23	38.80	<sup>a</sup> APO-Modafinil [TX]	<sup>a</sup> Modafin [RW]
						<sup>a</sup> Modafinil AN [EA]	<sup>a</sup> Modafinil Mylan [AF]
						<sup>a</sup> Modafinil Sandoz [SZ]	<sup>a</sup> Modavigil [TB]

**ANTI-DEMENTIA DRUGS**

*Anticholinesterases*

▪ **DONEPEZIL**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4219**

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**donepezil hydrochloride 5 mg tablet, 28**

2532G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.15	22.36	<sup>a</sup> APO-Donepezil [TX]	<sup>a</sup> Arazil [AF]
						<sup>a</sup> Aridon 5 [RW]	<sup>a</sup> Aridon APN 5 [RF]
						<sup>a</sup> Chem mart Donepezil [CH]	<sup>a</sup> Donepezil AN [EA]
						<sup>a</sup> Donepezil-DRLA [RZ]	<sup>a</sup> Donepezil-GA [ED]
						<sup>a</sup> Donepezil generichealth [GQ]	<sup>a</sup> Donepezil Sandoz [SZ]
						<sup>a</sup> Terry White Chemists Donepezil [TW]	
			<sup>b</sup> 3.68	24.83	22.36	<sup>a</sup> Aricept [PF]	

**donepezil hydrochloride 10 mg tablet, 28**

2479L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.15	22.36	<sup>a</sup> APO-Donepezil [TX]	<sup>a</sup> Arazil [AF]
						<sup>a</sup> Aridon 10 [RW]	<sup>a</sup> Aridon APN 10 [RF]
						<sup>a</sup> Chem mart Donepezil [CH]	<sup>a</sup> Donepezil AN [EA]
						<sup>a</sup> Donepezil-DRLA [RZ]	<sup>a</sup> Donepezil-GA [ED]
						<sup>a</sup> Donepezil generichealth [GQ]	<sup>a</sup> Donepezil RBX [RA]
						<sup>a</sup> Donepezil Sandoz [SZ]	<sup>a</sup> Pharmacor Donepezil 10 [CR]

			<sup>a</sup> Terry White Chemists Donepezil [TW]
<sup>b</sup> 9.00	30.15	22.36	<sup>a</sup> Aricept [PF]

▪ **DONEPEZIL**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**donepezil hydrochloride 5 mg tablet, 28**

8495D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.15	22.36	<sup>a</sup> APO-Donepezil [TX] <sup>a</sup> Aridon 5 [RW] <sup>a</sup> Chem mart Donepezil [CH] <sup>a</sup> Donepezil-DRLA [RZ] <sup>a</sup> Donepezil generichealth [GQ] <sup>a</sup> Terry White Chemists Donepezil [TW]	<sup>a</sup> Arazil [AF] <sup>a</sup> Aridon APN 5 [RF] <sup>a</sup> Donepezil AN [EA] <sup>a</sup> Donepezil-GA [ED] <sup>a</sup> Donepezil Sandoz [SZ]
			<sup>b</sup> 3.68	24.83	22.36	<sup>a</sup> Aricept [PF]	

**donepezil hydrochloride 10 mg tablet, 28**

8496E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.15	22.36	<sup>a</sup> APO-Donepezil [TX]	<sup>a</sup> Arazil [AF]

<sup>a</sup> Aridon 10 [RW]	<sup>a</sup> Aridon APN 10 [RF]
<sup>a</sup> Chem mart Donepezil [CH]	<sup>a</sup> Donepezil AN [EA]
<sup>a</sup> Donepezil-DRLA [RZ]	<sup>a</sup> Donepezil-GA [ED]
<sup>a</sup> Donepezil generichealth [GQ]	<sup>a</sup> Donepezil RBX [RA]
<sup>a</sup> Donepezil Sandoz [SZ]	<sup>a</sup> Pharmacor Donepezil 10 [CR]
<sup>a</sup> Terry White Chemists Donepezil [TW]	
<sup>b</sup> 9.00      30.15      22.36 <sup>a</sup> Aricept [PF]	

**■ GALANTAMINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4219**

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**galantamine 16 mg modified release capsule, 28**

2537M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	37.85	38.80	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]	<sup>a</sup> Galantamine AN SR [EA] <sup>a</sup> Gamine XR [RW]

**galantamine 8 mg modified release capsule, 28**

2463P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	32.97	34.18	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]	<sup>a</sup> Galantamine AN SR [EA] <sup>a</sup> Gamine XR [RW]

**galantamine 24 mg modified release capsule, 28**

2531F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	42.98	38.80	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]	<sup>a</sup> Galantamine AN SR [EA] <sup>a</sup> Gamine XR [RW]

**■ GALANTAMINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**galantamine 16 mg modified release capsule, 28**

8771P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.85	38.80	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]	<sup>a</sup> Galantamine AN SR [EA] <sup>a</sup> Gamine XR [RW]

**galantamine 8 mg modified release capsule, 28**

8770N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	32.97	34.18	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]	<sup>a</sup> Galantamine AN SR [EA] <sup>a</sup> Gamine XR [RW]

**galantamine 24 mg modified release capsule, 28**

8772Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	42.98	38.80	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]	<sup>a</sup> Galantamine AN SR [EA] <sup>a</sup> Gamine XR [RW]

▪ **RIVASTIGMINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4219**

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.  
Clinically meaningful response to treatment is demonstrated in the following areas:  
Patient's quality of life including but not limited to level of independence and happiness;  
Patient's cognitive function including but not limited to memory, recognition and interest in environment;  
Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**rivastigmine 4.6 mg/24 hours patch, 30**

2477J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.59	38.80	<sup>a</sup> Exelon Patch 5 [NV]	<sup>a</sup> Rivastigmelon Patch 5 [AF]

**rivastigmine 13.3 mg/24 hours patch, 30**

10538P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	80.59	38.80	Exelon Patch 15 [NV]

**rivastigmine 1.5 mg capsule, 56**

2475G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.31	38.80	Exelon [NV]

**rivastigmine 6 mg capsule, 56**

2526Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.31	38.80	Exelon [NV]

**rivastigmine 4.5 mg capsule, 56**

2494G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.31	38.80	Exelon [NV]

**rivastigmine 3 mg capsule, 56**

2493F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.31	38.80	Exelon [NV]

**rivastigmine 9.5 mg/24 hours patch, 30**

2551G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.59	38.80	<sup>a</sup> Exelon Patch 10 [NV]	<sup>a</sup> Rivastigmelon Patch 10 [AF]

**■ RIVASTIGMINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

### rivastigmine 4.6 mg/24 hours patch, 30

9161E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.59	38.80	<sup>a</sup> Exelon Patch 5 [NV]	<sup>a</sup> Rivastigmelon Patch 5 [AF]

### rivastigmine 13.3 mg/24 hours patch, 30

10541T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	80.59	38.80	Exelon Patch 15 [NV]

### rivastigmine 1.5 mg capsule, 56

8497F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.31	38.80	Exelon [NV]

### rivastigmine 6 mg capsule, 56

8500J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.31	38.80	Exelon [NV]

### rivastigmine 4.5 mg capsule, 56

8499H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.31	38.80	Exelon [NV]

### rivastigmine 3 mg capsule, 56

8498G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.31	38.80	Exelon [NV]

### rivastigmine 9.5 mg/24 hours patch, 30

9162F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.59	38.80	<sup>a</sup> Exelon Patch 10 [NV]	<sup>a</sup> Rivastigmelon Patch 10 [AF]

### Other anti-dementia drugs

## MEMANTINE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

#### 4214

Moderately severe Alzheimer disease

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:  
 Patient's quality of life including but not limited to level of independence and happiness;  
 Patient's cognitive function including but not limited to memory, recognition and interest in environment;  
 Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**memantine hydrochloride 20 mg tablet, 28**

2513G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.29	38.80	<sup>a</sup> APO-Memantine [TX] <sup>a</sup> Memantine generichealth [GQ]	<sup>a</sup> Ebixa [LU] <sup>a</sup> Memantine RBX [RA]

**memantine hydrochloride 10 mg tablet, 56**

2492E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.29	38.80	<sup>a</sup> APO-Memantine [TX] <sup>a</sup> Memantine generichealth [GQ] <sup>a</sup> Memanxa [RW]	<sup>a</sup> Ebixa [LU] <sup>a</sup> Memantine RBX [RA]

**MEMANTINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**memantine hydrochloride 20 mg tablet, 28**

9306T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	41.29	38.80	<sup>a</sup> APO-Memantine [TX] <sup>a</sup> Memantine generichealth [GQ]	<sup>a</sup> Ebixa [LU] <sup>a</sup> Memantine RBX [RA]

**memantine hydrochloride 10 mg tablet, 56**

1956Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	41.29	38.80	<sup>a</sup> APO-Memantine [TX] <sup>a</sup> Memantine generichealth [GQ] <sup>a</sup> Memanxa [RW]	<sup>a</sup> Ebixa [LU] <sup>a</sup> Memantine RBX [RA]

## OTHER NERVOUS SYSTEM DRUGS

### PARASYMPATHOMIMETICS

#### Anticholinesterases

#### ■ PYRIDOSTIGMINE

**PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50**

2724J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*24.79	26.00	Mestinon [IA]

**pyridostigmine bromide 180 mg modified release tablet, 50**

2608G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*134.41	38.80	Mestinon Timespan [IA]

**pyridostigmine bromide 60 mg tablet, 150**

1959D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	67.14	38.80	Mestinon [IA]

#### Choline esters

#### ■ BETHANECHOL

**bethanechol chloride 10 mg tablet, 100**

1062X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	37.92	38.80	Uro-Carb [YN]

## DRUGS USED IN ADDICTIVE DISORDERS

### Drugs used in nicotine dependence

#### ■ BUPROPION

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

**6881**

Nicotine dependence

Treatment Phase: Completion of a short-term (9 weeks) course of treatment

#### Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

#### Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**bupropion hydrochloride 150 mg modified release tablet, 90**

8710K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	165.40	38.80	Zyban [AS]

#### ■ BUPROPION

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6882**

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**bupropion hydrochloride 150 mg modified release tablet, 30**

8465M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	62.53	38.80	Zyban [AS]

▪ **NICOTINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**nicotine 21 mg/24 hours patch, 28**

3414Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	53.17	38.80	Nicotinell Step 1 [ON]

**nicotine 14 mg/24 hours patch, 28**

5572G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	53.17	38.80	Nicotinell Step 2 [ON]

**nicotine 7 mg/24 hours patch, 28**

5573H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	53.17	38.80	Nicotinell Step 3 [ON]

▪ **NICOTINE**

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**nicotine 21 mg/24 hours patch, 28**

5571F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	53.17	38.80	Nicotinell Step 1 [ON]

## ▪ NICOTINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Restricted benefit**

Nicotine dependence

#### **Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

#### **Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

### **Restricted benefit**

Nicotine dependence

#### **Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

#### **Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

### nicotine 21 mg/24 hours patch, 28

5465P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	53.17	38.80	Nicabate P [GC]

### nicotine 25 mg/16 hours patch, 28

10076H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	53.17	38.80	nicorette 16hr Invisipatch [JT]

## ▪ VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required (STREAMLINED)**

**6885**

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

#### **Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

#### **Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

### varenicline 1 mg tablet, 56

5469W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	109.55	38.80	Champix [PF]

## ▪ VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required (STREAMLINED)**

**6864**

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**varenicline 1 mg tablet, 56**

9129L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*208.61	38.80	Champix [PF]

**■ VARENICLINE**

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****6871**

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53**

9128K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	94.60	38.80	Champix [PF]

***Drugs used in alcohol dependence*****■ ACAMPROSATE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****5366**

Alcohol dependence

**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**acamprosate calcium 333 mg enteric tablet, 180**

8357W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	149.41	38.80	Campral [AF]

**■ NALTREXONE**

**Caution** Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Alcohol dependence

**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**naltrexone hydrochloride 50 mg tablet, 30**

8370M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	128.59	38.80	<sup>a</sup> APO-Naltrexone [TX]	<sup>a</sup> Naltrexone GH [GQ]

<sup>a</sup> ReVia [BQ]**OTHER NERVOUS SYSTEM DRUGS***Other nervous system drugs***■ DIMETHYL FUMARATE****Note** Special Pricing Arrangements apply.**Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

2943X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*969.23	38.80	Tecfidera [BD]

**■ DIMETHYL FUMARATE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 240 mg enteric capsule, 56**

2966D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1871.14	38.80	Tecfidera [BD]

**■ DIMETHYL FUMARATE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Authority required**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

## ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

General

### dimethyl fumarate 120 mg enteric capsule, 14

2896K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*969.23	38.80	Tecfidera [BD]

### ▪ RILUZOLE

#### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required

Amyotrophic lateral sclerosis

Treatment Phase: Initial treatment

#### Clinical criteria:

- The condition must be diagnosed by a neurologist, **AND**
- Patient must not have had the disease for more than 5 years, **AND**
- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

#### Authority required

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

### riluzole 50 mg tablet, 56

8664B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	203.32	38.80	<sup>a</sup> APO-Riluzole [TX] <sup>a</sup> Rilutek [SW]	<sup>a</sup> Pharmacor Riluzole [CR] <sup>a</sup> Riluzole Sandoz [SZ]

### ▪ TETRABENAZINE

#### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**5340**

Hyperkinetic extrapyramidal disorders

### tetrabenazine 25 mg tablet, 112

1330B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	338.60	38.80	iNova Pharmaceuticals (Australia) Pty Ltd [IA]

## ▪ ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

## ▪ ANTIPROTOZOALS

### AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

*Other agents against amoebiasis and other protozoal diseases*

### ▪ ATOVAQUONE

#### Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**5609**

Mild to moderate Pneumocystis carinii pneumonia

**Population criteria:**

- Patient must be an adult, **AND**
- Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

**atovaquone 750 mg/5 mL oral liquid, 210 mL**

8300W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	976.85	38.80	Wellvone [AS]

**■ PYRIMETHAMINE****pyrimethamine 25 mg tablet, 50**

1966L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	19.32	20.53	Daraprim [RW]

**ANTIMALARIALS***Biguanides***■ ATOVAQUONE + PROGUANIL**

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Confirmed or suspected Plasmodium falciparum malaria

**Population criteria:**

- Patient must be aged 3 years or older.

**Clinical criteria:**

- The treatment must be used where quinine containing regimens are inappropriate.

**atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12**

9439T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	66.16	38.80	Malarone [GK]

*Methanolquinolines***■ QUININE**

**Caution** Severe thrombocytopenia has been reported with this drug.

**Authority required (STREAMLINED)**

**5633**

Malaria

**quinine sulfate 300 mg tablet, 50**

1975Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	19.91	21.12	Quinate [RW]

*Artemisinin and derivatives, combinations***■ ARTEMETHER + LUMEFANTRINE**

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**

Confirmed or suspected Plasmodium falciparum malaria

**Clinical criteria:**

- Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

**artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18**

5296R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	89.24	38.80	Riamet 20mg/120mg Dispersible [SZ]

**■ ARTEMETHER + LUMEFANTRINE**

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**

Confirmed or suspected Plasmodium falciparum malaria

**artemether 20 mg + lumefantrine 120 mg tablet, 24**

9498X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	89.24	38.80	Riamet [SZ]

## ANTHELMINTICS

### ANTITREMATODALS

#### Quinoline derivatives and related substances

#### ■ PRAZIQUANTEL

##### Authority required (STREAMLINED)

**5659**

Schistosomiasis

##### praziquantel 600 mg tablet, 8

9447F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	39.54	38.80	Biltricide [BN]

### ANTINEMATODAL AGENTS

#### Benzimidazole derivatives

#### ■ ALBENDAZOLE

##### Authority required (STREAMLINED)

**5607**

Hydatid disease

##### Clinical criteria:

- The treatment must be in conjunction with surgery; OR
- The treatment must be used when a surgical cure cannot be achieved; OR
- The treatment must be used when surgery cannot be used.

##### albendazole 400 mg chewable tablet, 60

8459F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	165.53	38.80	Eskazole [AS]

#### ■ ALBENDAZOLE

##### Authority required (STREAMLINED)

**5680**

Tapeworm infestation

##### albendazole 200 mg chewable tablet, 6

8503M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	33.13	34.34	Zentel [AS]

#### ■ ALBENDAZOLE

##### Authority required (STREAMLINED)

**5817**

Whipworm infestation

##### Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

##### Authority required (STREAMLINED)

**5712**

Strongyloidiasis

##### Authority required (STREAMLINED)

**5797**

Hookworm infestation

##### albendazole 200 mg chewable tablet, 6

9047E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	33.13	34.34	Zentel [AS]

#### Tetrahydropyrimidine derivatives

#### ■ PYRANTEL

##### pyrantel 125 mg tablet, 6

3047J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.84	19.05	Anthel 125 [AF]

##### pyrantel 250 mg tablet, 6

3048K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	24.61	25.82	Anthel 250 [AF]

#### Avermectines

## ■ IVERMECTIN

### Authority required (STREAMLINED)

**4319**

Onchocerciasis

### ivermectin 3 mg tablet, 4

8359Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	31.65	32.86	Stromectol [MK]

## ■ IVERMECTIN

### Authority required (STREAMLINED)

**4328**

Strongyloidiasis

### Authority required (STREAMLINED)

**4565**

Crusted (Norwegian) scabies

### Clinical criteria:

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; OR
- Patient must have a contraindication to topical treatment.

### Population criteria:

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

### Authority required (STREAMLINED)

**4566**

Human sarcoptic scabies

### Clinical criteria:

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR
- Patient must have a contraindication to topical treatment.

### Population criteria:

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**Note** This drug is not PBS-subsidised for first line treatment of typical scabies.

### ivermectin 3 mg tablet, 4

2868Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*52.21	38.80	Stromectol [MK]

## ■ ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

### ECTOPARASITICIDES, INCL. SCABICIDES

*Pyrethrines, incl. synthetic compounds*

## ■ PERMETHRIN

### permethrin 5% cream, 30 g

3054R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	19.64	20.85	Lyclear [JT]

## ■ RESPIRATORY SYSTEM

## ■ NASAL PREPARATIONS

### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

*Other nasal preparations*

## ■ MUPIROCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**6647**

Staphylococcus aureus infection

### Clinical criteria:

- Patient must have nasal colonisation with the bacteria.

### Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

**mupirocin 2% (20 mg/g) ointment, 3 g**

8440W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	24.61	25.82	Bactroban [GK]

## DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

**ADRENERGICS, INHALANTS***Selective beta-2-adrenoreceptor agonists*

### EFORMOTEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**eformoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules**

8136F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	36.63	37.84	Foradile [SZ]

**eformoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

8240Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	35.88	37.09	Oxis Turbuhaler [AP]

**eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

8239P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	27.58	28.79	Oxis Turbuhaler [AP]

### INDACATEROL

**Note** This drug is not PBS-subsidised for the treatment of asthma.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**indacaterol 300 microgram powder for inhalation, 30 capsules**

5137J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.42	38.80	Onbrez [NV]

**indacaterol 150 microgram powder for inhalation, 30 capsules**

5134F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.42	38.80	Onbrez [NV]

### SALBUTAMOL

**salbutamol 100 microgram/actuation pressurised inhalation, 200 actuations**

8288F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.51	19.72	<sup>a</sup> Asmol CFC-free [AL]
			<sup>b</sup> 2.54	*21.05	19.72	<sup>a</sup> Ventolin CFC-free [GK]

**salbutamol 200 microgram powder for inhalation, 128 capsules**

10143W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*21.83	23.04	Ventolin Rotacaps [GK]

### SALBUTAMOL

**Restricted benefit**

Bronchospasm

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1**

8354Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*39.07	38.80	Airomir Autohaler [IA]

## ■ SALBUTAMOL

**Note** Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution.

### Restricted benefit

Asthma

#### Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

#### Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

### salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11095Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	<sup>B</sup> 0.99	*20.50	20.72	<sup>a</sup> Ventolin Nebules [GK]

### salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

2000G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.09	20.30	<sup>a</sup> APO-Salbutamol [TX] <sup>a</sup> Salbutamol Actavis [EA] <sup>a</sup> Salbutamol Sandoz [SZ]	<sup>a</sup> Butamol 2.5 [QA] <sup>a</sup> Salbutamol AN [JU]
			<sup>B</sup> 0.50	*19.59	20.30	<sup>a</sup> Asmol 2.5 uni-dose [AF]	

### salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

2001H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.51	20.72	<sup>a</sup> APO-Salbutamol [TX] <sup>a</sup> Salbutamol Actavis [EA] <sup>a</sup> Salbutamol Sandoz [SZ]	<sup>a</sup> Butamol 5 [QA] <sup>a</sup> Salbutamol AN [JU]
			<sup>B</sup> 0.50	*20.01	20.72	<sup>a</sup> Asmol 5 uni-dose [AF]	

### salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11130T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	<sup>B</sup> 1.02	*20.11	20.30	<sup>a</sup> Ventolin Nebules [GK]

## ■ SALMETEROL

### Restricted benefit

Asthma

#### Clinical criteria:

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

### salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8141L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	36.63	37.84	Serevent Accuhaler [GK]

## ■ TERBUTALINE

### terbutaline sulfate 500 microgram/actuation powder for inhalation, 100 actuations

2817G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.53	21.74	Bricanyl Turbuhaler [AP]

*Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics*

## ■ BUDESONIDE + EFORMOTEROL

### Restricted benefit

Asthma

#### Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

#### Population criteria:

- Patient must be aged 12 years or over.

**budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

8796Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	54.64	38.80	Symbicort Turbuhaler 100/6 [AP]

**budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

8625Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	58.68	38.80	Symbicort Turbuhaler 200/6 [AP]

**■ BUDESONIDE + EFORMOTEROL****Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**

- Patient must be aged 12 years or over.

**budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations**

10015D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*56.29	38.80	Symbicort Rapihaler 100/3 [AP]

**budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations**

10024N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*52.47	38.80	Symbicort Rapihaler 50/3 [AP]

**■ BUDESONIDE + EFORMOTEROL****Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 120 actuations**

8750M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	86.19	38.80	Symbicort Turbuhaler 400/12 [AP]

**■ BUDESONIDE + EFORMOTEROL****Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

### budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation pressurised inhalation, 120 actuations

10018G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*82.45	38.80	Symbicort Rapihaler 200/6 [AP]

### FLUTICASONE + EFORMOTEROL

**Note** Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

### fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation pressurised inhalation, 120 actuations

10008R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	64.07	38.80	flutiform 250/10 [MF]

### fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations

2827T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	40.24	38.80	flutiform 50/5 [MF]

### fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations

10007Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	48.10	38.80	flutiform 125/5 [MF]

### FLUTICASONE + SALMETEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

### fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8430Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	41.56	38.80	Seretide Accuhaler 100/50 [GK]

**fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations**

8517G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	41.56	38.80	Seretide MDI 50/25 [GK]

**fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations**

8518H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	48.25	38.80	<sup>a</sup> Fluticasone + Salmeterol Cipla 125/25 [LR]	<sup>a</sup> SalplusF Inhaler 125/25 [YC]
						<sup>a</sup> Seretide MDI 125/25 [GK]	

**fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

8431R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	48.25	38.80	Seretide Accuhaler 250/50 [GK]

**FLUTICASONE + SALMETEROL****Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.**fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

8432T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	61.39	38.80	Seretide Accuhaler 500/50 [GK]

**fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations**

8519J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	61.39	38.80	<sup>a</sup> Fluticasone + Salmeterol Cipla 250/25 [LR]	<sup>a</sup> SalplusF Inhaler 250/25 [YC]
						<sup>a</sup> Seretide MDI 250/25 [GK]	

**FLUTICASONE FUROATE + VILANTEROL****Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

11129R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	71.62	38.80	Breo Ellipta 200/25 [GK]

## FLUTICASONE FUROATE + VILANTEROL

### Restricted benefit

Asthma

### Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

### Population criteria:

- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

### Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

## fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11124L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	56.12	38.80	Breo Ellipta 100/25 [GK]

*Adrenergics in combination with anticholinergics*

## ACLIDINIUM + EFORMOTEROL

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

### Authority required (STREAMLINED)

5763

Chronic obstructive pulmonary disease (COPD)

### Clinical criteria:

- Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

## aclidinium 340 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations

10565C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	91.18	38.80	Brimica Genuair [FK]

## INDACATEROL + GLYCOPYRRONIUM

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

### Authority required (STREAMLINED)

5763

Chronic obstructive pulmonary disease (COPD)

### Clinical criteria:

- Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

## indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules

10156M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	90.53	38.80	ultibro breezhaler 110/50 [NV]

## TIOTROPIUM + OLODATEROL

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Authority required (STREAMLINED)****5763**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations**

10557P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	90.01	38.80	Spolto Respimat [BY]

**■ UMECLIDINIUM + VILANTEROL****Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.**Note** This product is not PBS-subsidised for the treatment of asthma.**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.**Authority required (STREAMLINED)****5763**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

10188F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	92.56	38.80	Anoro Ellipta 62.5/25 [GK]

**OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS***Glucocorticoids***■ BECLOMETASONE****beclometasone dipropionate 50 microgram/actuation pressurised inhalation, 200 actuations**

8406K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	21.72	22.93	Qvar 50 [IA]

**beclometasone dipropionate 100 microgram/actuation pressurised inhalation, 200 actuations**

8407L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	33.43	34.64	Qvar 100 [IA]

**■ BECLOMETASONE****Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1**

8409N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	38.11	38.80	Qvar 100 Autohaler [IA]

**BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1**

8408M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	28.81	30.02	Qvar 50 Autohaler [IA]

**■ BUDESONIDE****budesonide 100 microgram/actuation powder for inhalation, 200 actuations**

2070Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	25.07	26.28	Pulmicort Turbuhaler [AP]

**budesonide 200 microgram/actuation powder for inhalation, 200 actuations**

2071B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	31.45	32.66	Pulmicort Turbuhaler [AP]

**budesonide 400 microgram/actuation powder for inhalation, 200 actuations**

2072C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	44.27	38.80	Pulmicort Turbuhaler [AP]

**■ BUDESONIDE****Authority required (STREAMLINED)****6340**

Severe chronic asthma

**Clinical criteria:**

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

**budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

2065Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	37.07	38.28	Pulmicort Respules [AP]

**budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules**

2066R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	47.27	38.80	Pulmicort Respules [AP]

**■ CICLESONIDE****ciclesonide 160 microgram/actuation pressurised inhalation, 120 actuations**

8854B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	40.85	38.80	Alvesco 160 [AP]

**ciclesonide 80 microgram/actuation pressurised inhalation, 120 actuations**

8853Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	27.39	28.60	Alvesco 80 [AP]

**■ FLUTICASONE****fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations**

8147T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	18.50	19.71	Flixotide Junior Accuhaler [GK]

**fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations**

8148W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	27.92	29.13	Flixotide Accuhaler [GK]

**fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations**

8149X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	42.06	38.80	Flixotide Accuhaler [GK]

**fluticasone propionate 50 microgram/actuation pressurised inhalation, 120 actuations**

8516F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	18.50	19.71	Flixotide Junior [GK]

**fluticasone propionate 125 microgram/actuation pressurised inhalation, 120 actuations**

8345F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	27.92	29.13	<sup>a</sup> Flixotide [GK]	<sup>a</sup> Fluticasone Cipla Inhaler [LR]

**fluticasone propionate 250 microgram/actuation pressurised inhalation, 120 actuations**

8346G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	1	..	42.06	38.80	<sup>a</sup> Flixotide [GK]	<sup>a</sup> Fluticasone Cipla Inhaler [LR]

**Anticholinergics****■ ACLIDINIUM****Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations**

10124W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	61.97	38.80	Bretaris Genuair [FK]

## ■ GLYCOPYRRONIUM

### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

#### glycopyrronium 50 microgram powder for inhalation, 30 capsules

10059K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	61.97	38.80	seebri breezhaler [NV]

## ■ IPRATROPIUM

#### ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations

8671J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*34.93	36.14	Atrovent [BY]

## ■ IPRATROPIUM

### Restricted benefit

Asthma

#### Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

#### Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

#### ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules

1542E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*27.33	28.54	<sup>a</sup> Aeron 250 [QA] <sup>a</sup> Ipratrin [AF]	<sup>a</sup> APO-Ipratropium [TX]
			<sup>b</sup> 0.50	*27.83	28.54	<sup>a</sup> Atrovent [BY]	

#### ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules

8238N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*30.27	31.48	<sup>a</sup> Aeron 500 [QA] <sup>a</sup> Ipratrin Adult [AF]	<sup>a</sup> APO-Ipratropium [TX]
			<sup>b</sup> 0.50	*30.77	31.48	<sup>a</sup> Atrovent Adult [BY]	

## ■ TIOTROPIUM

### Restricted benefit

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

#### tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

10509D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	59.42	38.80	Spiriva Respimat [BY]

## ■ TIOTROPIUM

### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

#### tiotropium 18 microgram powder for inhalation, 30 capsules

8626B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.42	38.80	Spiriva [BY]

## ■ TIOTROPIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### Restricted benefit

Severe asthma

#### Clinical criteria:

- Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid and a long acting beta-2 agonist.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

11043F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	59.42	38.80	Spiriva Respimat [BY]

**■ UMECLIDINIUM****Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations**

10187E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	61.97	38.80	Incruse Ellipta [GK]

*Antiallergic agents, excl. corticosteroids***■ CROMOGLYCAT****sodium cromoglycate 5 mg/actuation pressurised inhalation, 112 actuations**

8334P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	38.82	38.80	Intal Forte CFC-Free [SW]

**sodium cromoglycate 20 mg powder for inhalation, 100 capsules**

2878L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.82	34.03	Intal Spincaps [EA]

**sodium cromoglycate 1 mg/actuation pressurised inhalation, 200 actuations**

8767K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	34.64	35.85	Intal CFC-Free [SW]

**■ NEDOCROMIL****nedocromil sodium 2 mg/actuation pressurised inhalation, 112 actuations**

8365G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	38.72	38.80	Tilade CFC-Free [SW]

**ADRENERGICS FOR SYSTEMIC USE***Alpha- and beta-adrenoreceptor agonists***■ ADRENALINE****adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

1016L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	22.58	23.79	Link Medical Products Pty Ltd [LM]

**adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

5004J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	22.58	23.79	Link Medical Products Pty Ltd [LM]

**■ ADRENALINE****Caution** EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.**Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at [www.allergy.org.au](http://www.allergy.org.au).)**Note** Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.**Note** No applications for repeats will be authorised.**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**adrenaline 300 microgram/0.3 mL injection, 1 dose**

8698T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	97.10	38.80	EpiPen [AL]

**adrenaline 150 microgram/0.3 mL injection, 1 dose**

8697R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	97.10	38.80	EpiPen Jr. [AL]

*Selective beta-2-adrenoreceptor agonists*

▪ **SALBUTAMOL**

**salbutamol 2 mg/5 mL oral liquid, 150 mL**

1103C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.81	26.02	Ventolin [GK]

▪ **TERBUTALINE**

**terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules**

1034K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	31.06	32.27	Bricanyl [AP]

**OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES**

*Xanthines*

▪ **THEOPHYLLINE**

**Caution** Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**theophylline 300 mg modified release tablet, 100**

8231F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.94	19.15	Nuelin-SR 300 [IA]

**theophylline 200 mg modified release tablet, 100**

8230E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.83	17.04	Nuelin-SR 200 [IA]

**theophylline 250 mg modified release tablet, 100**

2634P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.79	18.00	Nuelin-SR 250 [IA]

**theophylline 133.3 mg/25 mL oral liquid, 500 mL**

2614N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	16.68	17.89	Nuelin [IA]

*Leukotriene receptor antagonists*

▪ **MONTELUKAST**

**Note** This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

**Note** This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6666**

Asthma

Treatment Phase: First-line prevention

**Population criteria:**

- Patient must be aged 2 to 5 years inclusive.

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**montelukast 4 mg chewable tablet, 28**

8627C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.24	19.45	<sup>a</sup> APO-Montelukast [TX] <sup>a</sup> Chem mart Montelukast [CH] <sup>a</sup> Montelukast AN [EA] <sup>a</sup> Montelukast Sandoz 4 [SZ] <sup>a</sup> Terry White Chemists Montelukast [TW]	<sup>a</sup> Auro-Montelukast Tabs 4 [DO] <sup>a</sup> Lukair [AL] <sup>a</sup> Montelukast GH [GQ] <sup>a</sup> Respikast 4 [RW]
			<sup>b</sup> 3.00	21.24	19.45	<sup>a</sup> Singulair [MK]	

▪ **MONTELUKAST**

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6674**

Asthma

Treatment Phase: First-line prevention

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**Authority required (STREAMLINED)**

**6684**

Asthma

Treatment Phase: Prevention of condition

**Clinical criteria:**

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be as an alternative to adding eformoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**montelukast 5 mg chewable tablet, 28**

8628D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.82	19.03	<sup>a</sup> APO-Montelukast [TX] <sup>a</sup> Chem mart Montelukast [CH] <sup>a</sup> Montelukast AN [EA] <sup>a</sup> Montelukast Sandoz 5 [SZ] <sup>a</sup> Terry White Chemists Montelukast [TW]	<sup>a</sup> Auro-Montelukast Tabs 5 [DO] <sup>a</sup> Lukair [AL] <sup>a</sup> Montelukast GH [GQ] <sup>a</sup> Respikast 5 [RW]
			<sup>b</sup> 3.00	20.82	19.03	<sup>a</sup> Singulair [MK]	

■ **COUGH AND COLD PREPARATIONS**

**COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS**

*Opium alkaloids and derivatives*

■ **CODEINE**

codeine phosphate 30 mg tablet, 20

1214X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	20.50	21.71	Fawns and McAllan Proprietary Limited [FM]

■ **ANTIHISTAMINES FOR SYSTEMIC USE**

**ANTIHISTAMINES FOR SYSTEMIC USE**

*Phenothiazine derivatives*

■ **PROMETHAZINE**

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

1948M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*38.67	38.80	Hospira Pty Limited [PF]

■ **SENSORY ORGANS**

■ **OPHTHALMOLOGICALS**

**ANTIINFECTIVES**

*Antibiotics*

■ **AZITHROMYCIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

Restricted benefit

Trachoma

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	#26.26	27.83	Zithromax [PF]

azithromycin 500 mg tablet, 2

8336R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.37	16.58	<sup>a</sup> APO-Azithromycin [TX] <sup>a</sup> Azithromycin Sandoz [SZ] <sup>a</sup> Terry White Chemists Azithromycin [TW]	<sup>a</sup> Azithromycin Mylan [AF] <sup>a</sup> Chem mart Azithromycin [CH] <sup>a</sup> Zithromax [PF]

■ **CHLORAMPHENICOL**

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

chloramphenicol 0.5% eye drops, 10 mL

11112W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP MW	‡1	2	..	15.07	16.28	Chlorsig [QA]

■ **GENTAMICIN**

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected Pseudomonas eye infection

gentamicin 0.3% eye drops, 5 mL

5566Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	2	..	21.41	22.62	Genoptic [AG]

■ **GENTAMICIN**

Restricted benefit

Invasive ocular infection

Restricted benefit

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

**gentamicin 0.3% eye drops, 5 mL**

1441W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	21.41	22.62	Genoptic [AG]

▪ **TOBRAMYCIN**

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

**tobramycin 0.3% eye drops, 5 mL**

5569D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	2	..	21.71	22.92	Tobrex [NV]

**tobramycin 0.3% eye ointment, 3.5 g**

5570E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	..	..	24.27	25.48	Tobrex [NV]

▪ **TOBRAMYCIN**

**Restricted benefit**

Invasive ocular infection

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

**tobramycin 0.3% eye drops, 5 mL**

2328M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	21.71	22.92	Tobrex [NV]

**tobramycin 0.3% eye ointment, 3.5 g**

2329N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	24.27	25.48	Tobrex [NV]

*Antivirals*

▪ **ACICLOVIR**

**Restricted benefit**

Herpes simplex keratitis

**aciclovir 3% eye ointment, 4.5 g**

5501M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	..	..	38.08	38.80	Zovirax [GK]

▪ **ACICLOVIR**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Herpes simplex keratitis

**aciclovir 3% eye ointment, 4.5 g**

1002R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	38.08	38.80	Zovirax [GK]

*Fluoroquinolones*

▪ **CIPROFLOXACIN**

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

## SENSORY ORGANS

### ciprofloxacin 0.3% eye drops, 5 mL

1217C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*30.27	31.48	<sup>a</sup> CiloQuin [NM]
			<sup>B</sup> 4.36	*34.63	31.48	<sup>a</sup> Ciloxan [NV]

#### ■ CIPROFLOXACIN

##### Authority required

Bacterial keratitis

##### Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

### ciprofloxacin 0.3% eye drops, 5 mL

5564W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	2	..	..	*30.27	31.48	<sup>a</sup> CiloQuin [NM]
			<sup>B</sup> 4.36	*34.63	31.48	<sup>a</sup> Ciloxan [NV]

#### ■ OFLOXACIN

##### Authority required

Bacterial keratitis

##### Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

### ofloxacin 0.3% eye drops, 5 mL

5567B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	2	..	..	*34.95	36.16	Ocuflox [AG]

#### ■ OFLOXACIN

##### Authority required

Bacterial keratitis

##### Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

### ofloxacin 0.3% eye drops, 5 mL

8383F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*34.95	36.16	Ocuflox [AG]

## ANTIINFLAMMATORY AGENTS

### Corticosteroids, plain

#### ■ DEXAMETHASONE

### DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1

1288T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	2	..	14.73	15.94	Maxidex [NV]

#### ■ DEXAMETHASONE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

### DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1

5565X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	..	..	14.73	15.94	Maxidex [NV]

#### ■ DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

##### Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

##### Treatment criteria:

- Must be treated by an ophthalmologist.

##### Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**

- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must be unsuitable for treatment with VEGF inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Grandfathering treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2016, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

## SENSORY ORGANS

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

### dexamethasone 700 microgram implant, 1

10943Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1354.79	38.80	Ozurdex [AG]

### ■ FLUOROMETHOLONE

#### fluorometholone 0.1% eye drops, 5 mL

1204J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	14.55	15.76	Flucon [NV]	FML Liquifilm [AG]

### ■ FLUOROMETHOLONE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

#### fluorometholone 0.1% eye drops, 5 mL

5513E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>OP</b>	±1	..	..	14.55	15.76	Flucon [NV]	FML Liquifilm [AG]

### ■ FLUOROMETHOLONE ACETATE

#### fluorometholone acetate 0.1% eye drops, 5 mL

1438Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	2	..	14.55	15.76	Flarex [NV]

### ■ FLUOROMETHOLONE ACETATE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

#### fluorometholone acetate 0.1% eye drops, 5 mL

5533F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	..	..	14.55	15.76	Flarex [NV]

### ■ HYDROCORTISONE ACETATE

#### hydrocortisone acetate 1% eye ointment, 5 g

2441L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	16.54	17.75	Hycor [QA]

### ■ HYDROCORTISONE ACETATE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

#### hydrocortisone acetate 1% eye ointment, 5 g

5516H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	..	..	16.54	17.75	Hycor [QA]

### *Corticosteroids and mydriatics in combination*

### ■ PREDNISOLONE ACETATE + PHENYLEPHRINE

#### Restricted benefit

Corneal grafts

#### Restricted benefit

Uveitis

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

3112T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	27.96	29.17	Prednefrin Forte [AG]

▪ **PREDNISOLONE ACETATE + PHENYLEPHRINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Uveitis

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

5568C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	..	..	27.96	29.17	Prednefrin Forte [AG]

**ANTIGLAUCOMA PREPARATIONS AND MIOTICS**

*Sympathomimetics in glaucoma therapy1)*

▪ **APRACLONIDINE**

**Restricted benefit**

Intra-ocular pressure

**Clinical criteria:**

- The treatment must be for short-term reduction of intra-ocular pressure, **AND**
- Patient must already be on maximally tolerated anti-glaucoma therapy.

**apraclonidine 0.5% eye drops, 10 mL**

8083K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	40.40	38.80	lopidine 0.5% [NV]

▪ **BRIMONIDINE**

**brimonidine tartrate 0.2% eye drops, 5 mL**

8351M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	23.02	24.23	<sup>a</sup> Enidin [PE]
			<sup>B</sup> 1.42	24.44	24.23	<sup>a</sup> Alphagan [AG]

**brimonidine tartrate 0.15% eye drops, 5 mL**

5298W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	23.02	24.23	Alphagan P 1.5 [AG]

▪ **BRIMONIDINE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brimonidine tartrate 0.2% eye drops, 5 mL**

5534G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	23.02	24.23	<sup>a</sup> Enidin [PE]
			<sup>B</sup> 1.42	24.44	24.23	<sup>a</sup> Alphagan [AG]

**brimonidine tartrate 0.15% eye drops, 5 mL**

5563T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	23.02	24.23	Alphagan P 1.5 [AG]

▪ **BRIMONIDINE + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

8826M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	28.14	29.35	Combigan [AG]

▪ **BRIMONIDINE + TIMOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

# SENSORY ORGANS

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

5535H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	28.14	29.35	Combigan [AG]

*Parasympathomimetics*

▪ **PILOCARPINE**

**pilocarpine hydrochloride 4% eye drops, 15 mL**

2598R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	19.97	21.18	Isopto Carpine [NV]

**pilocarpine hydrochloride 1% eye drops, 15 mL**

2595N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	16.40	17.61	Isopto Carpine [NV]

**pilocarpine hydrochloride 2% eye drops, 15 mL**

2596P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	17.49	18.70	Isopto Carpine [NV]

▪ **PILOCARPINE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**pilocarpine hydrochloride 4% eye drops, 15 mL**

5538L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	19.97	21.18	Isopto Carpine [NV]

**pilocarpine hydrochloride 1% eye drops, 15 mL**

5536J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	16.40	17.61	Isopto Carpine [NV]

**pilocarpine hydrochloride 2% eye drops, 15 mL**

5537K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	17.49	18.70	Isopto Carpine [NV]

*Carbonic anhydrase inhibitors*

▪ **ACETAZOLAMIDE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**acetazolamide 250 mg tablet, 100**

1004W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	3	..	26.91	28.12	Diamox [RW]

▪ **BRINZOLAMIDE**

**brinzolamide 1% eye drops, 5 mL**

8483L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	25.31	26.52	<sup>a</sup> BrinzoQuin [NM]
			<sup>B</sup> 4.78	30.09	26.52	<sup>a</sup> Azopt [NV]

▪ **BRINZOLAMIDE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 1% eye drops, 5 mL**

5540N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	25.31	26.52	<sup>a</sup> BrinzoQuin [NM]
			<sup>B</sup> 4.78	30.09	26.52	<sup>a</sup> Azopt [NV]

▪ **BRINZOLAMIDE + BRIMONIDINE**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

10536M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	27.65	28.86	Simbrinza 1%/0.2% [NV]

▪ **BRINZOLAMIDE + BRIMONIDINE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

10547D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	27.65	28.86	Simbrinza 1%/0.2% [NV]

▪ **BRINZOLAMIDE + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

3438Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	28.88	30.09	Azarga [NV]

▪ **BRINZOLAMIDE + TIMOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

5562R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	28.88	30.09	Azarga [NV]

▪ **DORZOLAMIDE**

**dorzolamide 2% eye drops, 5 mL**

8488R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	5	..	21.96	23.17	<sup>a</sup> Trusamide [QA]	<sup>a</sup> Trusopt [MF]

▪ **DORZOLAMIDE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**dorzolamide 2% eye drops, 5 mL**

5541P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	21.96	23.17	<sup>a</sup> Trusamide [QA]	<sup>a</sup> Trusopt [MF]

▪ **DORZOLAMIDE + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

8567X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	5	..	24.08	25.29	<sup>a</sup> Cosdor [QA]	<sup>a</sup> DORZOLAMIDE/TIMOLOL AN 20/5 [EA]
						<sup>a</sup> Dorzolamide/Timolol Sandoz 20/5 [SZ]	
			<sup>B</sup> 1.00	25.08	25.29	<sup>a</sup> Cosopt [MF]	

▪ **DORZOLAMIDE + TIMOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

5542Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	24.08	25.29	<sup>a</sup> Cosdor [QA]	<sup>a</sup> DORZOLAMIDE/TIMOLOL AN 20/5 [EA]
						<sup>a</sup> Dorzolamide/Timolol Sandoz 20/5 [SZ]	
			<sup>B</sup> 1.00	25.08	25.29	<sup>a</sup> Cosopt [MF]	

*Beta blocking agents1)*

▪ **BETAXOLOL**

**betaxolol 0.5% eye drops, 5 mL**

2825Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	18.35	19.56	<sup>a</sup> BetoQuin [NM]
			<sup>B</sup> 4.76	23.11	19.56	<sup>a</sup> Betoptic [NV]

**betaxolol 0.25% eye drops, 5 mL**

2811Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	18.35	19.56	Betoptic S [NV]

▪ **BETAXOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**betaxolol 0.5% eye drops, 5 mL**

5544T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	18.35	19.56	<sup>a</sup> BetoQuin [NM]
			<sup>B</sup> 4.76	23.11	19.56	<sup>a</sup> Betoptic [NV]

**betaxolol 0.25% eye drops, 5 mL**

5543R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	18.35	19.56	Betoptic S [NV]

▪ **TIMOLOL**

**timolol 0.5% eye drops, 5 mL**

1279H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	16.81	18.02	Timoptol [MF]

**timolol 0.1% eye gel, 5 g**

8803H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	19.34	20.55	Nyogel [AS]

**timolol 0.5% eye drops, 2.5 mL**

1926J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	16.87	18.08	Timoptol XE [MF]

**timolol 0.25% eye drops, 2.5 mL**

1925H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	16.69	17.90	Timoptol XE [MF]

▪ **TIMOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**timolol 0.5% eye drops, 5 mL**

5548B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	16.81	18.02	Timoptol [MF]

**timolol 0.1% eye gel, 5 g**

5546X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	19.34	20.55	Nyogel [AS]

**timolol 0.5% eye drops, 2.5 mL**

5550D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	16.87	18.08	Timoptol XE [MF]

**timolol 0.25% eye drops, 2.5 mL**

5549C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	16.69	17.90	Timoptol XE [MF]

*Prostaglandin analogues1)*

▪ **BIMATOPROST**

**bimatoprost 0.03% eye drops, 3 mL**

8620Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	5	..	36.01	37.22	<sup>a</sup> Bimatoprost Sandoz [SZ] <sup>a</sup> Lumigan [AG]	<sup>a</sup> Bimtop [QA]

**bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses**

10046R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	32.01	33.22	Lumigan PF [AG]

▪ **BIMATOPROST**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**bimatoprost 0.03% eye drops, 3 mL**

5551E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	36.01	37.22	<sup>a</sup> Bimatoprost Sandoz [SZ] <sup>a</sup> Lumigan [AG]	<sup>a</sup> Bimtop [QA]

**bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses**

10053D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	32.01	33.22	Lumigan PF [AG]

▪ **BIMATOPROST + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses**

10107Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	35.74	36.95	GANfort PF 0.3/5 [AG]

▪ **BIMATOPROST + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

## SENSORY ORGANS

### imatoprost 0.03% + timolol 0.5% eye drops, 3 mL

9464D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	40.46	38.80	Ganfort 0.3/5 [AG]

### ▪ BIMATOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

#### Restricted benefit

Elevated intra-ocular pressure

#### **Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### imatoprost 0.03% + timolol 0.5% eye drops, 3 mL

5558M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	40.46	38.80	Ganfort 0.3/5 [AG]

### imatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses

10108B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	35.74	36.95	GANfort PF 0.3/5 [AG]

### ▪ LATANOPROST

#### latanoprost 0.005% eye drops, 2.5 mL

8243W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	16.92	18.13	<sup>a</sup> APO-Latanoprost [TX] <sup>a</sup> Lanpro [JU] <sup>a</sup> Latanoprost GH [GQ] <sup>a</sup> Terry White Chemists Latanoprost [TW] <sup>a</sup> Xalatan [PF]	<sup>a</sup> Chem mart Latanoprost [CH] <sup>a</sup> Latanoprost Actavis [EA] <sup>a</sup> Latanoprost Sandoz [SZ] <sup>a</sup> Xalaprost [QA]

### ▪ LATANOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

#### latanoprost 0.005% eye drops, 2.5 mL

5552F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	16.92	18.13	<sup>a</sup> APO-Latanoprost [TX] <sup>a</sup> Lanpro [JU] <sup>a</sup> Latanoprost GH [GQ] <sup>a</sup> Terry White Chemists Latanoprost [TW] <sup>a</sup> Xalatan [PF]	<sup>a</sup> Chem mart Latanoprost [CH] <sup>a</sup> Latanoprost Actavis [EA] <sup>a</sup> Latanoprost Sandoz [SZ] <sup>a</sup> Xalaprost [QA]

### ▪ LATANOPROST + TIMOLOL

#### Restricted benefit

Elevated intra-ocular pressure

#### **Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

#### latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

8895E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	21.37	22.58	<sup>a</sup> APO-Latanoprost/Timolol 0.05/5 [TX] <sup>a</sup> Latanoprost/timolol AN 50/5 [EA] <sup>a</sup> Xalacom [PF]	<sup>a</sup> Lantim [JU] <sup>a</sup> Latanoprost/Timolol Sandoz 50/5 [SZ] <sup>a</sup> Xalamol 50/5 [QA]

### ▪ LATANOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

#### Restricted benefit

Elevated intra-ocular pressure

#### **Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR

- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

5553G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	21.37	22.58	<sup>a</sup> APO-Latanoprost/Timolol 0.05/5 [TX]	<sup>a</sup> Lantim [JU]
						<sup>a</sup> Latanoprost/timolol AN 50/5 [EA]	<sup>a</sup> Latanoprost/Timolol Sandoz 50/5 [SZ]
						<sup>a</sup> Xalacom [PF]	<sup>a</sup> Xalamol 50/5 [QA]

**▪ TAFLUPROST**
**tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses**

2755B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	34.92	36.13	Saflutan [MF]

**▪ TAFLUPROST**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses**

2748P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	34.92	36.13	Saflutan [MF]

**▪ TRAVOPROST**
**travoprost 0.004% eye drops, 2.5 mL**

8597L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	40.75	38.80	Travatan [NV]

**▪ TRAVOPROST**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**travoprost 0.004% eye drops, 2.5 mL**

5554H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	40.75	38.80	Travatan [NV]

**▪ TRAVOPROST + TIMOLOL**
**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

9057Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	45.21	38.80	Duotrav [NV]

**▪ TRAVOPROST + TIMOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

5555J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	45.21	38.80	Duotrav [NV]

**MYDRIATICS AND CYCLOPLEGICS**
*Anticholinergics*

▪ **ATROPINE SULFATE**

**ATROPINE Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL, 1**

1093M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	2	..	23.78	24.99	Atropt [QA]

**DECONGESTANTS AND ANTIALLERGICS**

*Other antiallergics*

▪ **CROMOGLYCATE**

**Restricted benefit**

Vernal kerato-conjunctivitis

**sodium cromoglycate 2% eye drops, 10 mL**

1127H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	17.86	19.07	Opticrom [SW]

**sodium cromoglycate 2% eye drops, 10 mL**

5529B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	17.86	19.07	Opticrom [SW]

**OCULAR VASCULAR DISORDER AGENTS**

*Antineovascularisation agents*

▪ **AFLIBERCEPT**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**

- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**afibercept 4 mg/0.1 mL injection, 0.1 mL vial**

10505X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1149.44	38.80	Eylea [BN]

**■ AFLIBERCEPT**

**Note** Special Pricing Arrangements apply.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR

- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.
- Authority approval for initial treatment of each eye must be sought.  
The first authority application for each eye must be made in writing or by telephone.  
A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Branch retinal vein occlusion with macular oedema  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema  
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.
- Authority approval for initial treatment of each eye must be sought.  
The first authority application for each eye must be made in writing or by telephone.  
A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**afibercept 4 mg/0.1 mL injection, 0.1 mL vial**

2168D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1149.44	38.80	Eylea [BN]

▪ **RANIBIZUMAB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**

- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe**

10374B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1149.44	38.80	<sup>a</sup> Lucentis [NV]

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

10373Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1149.44	38.80	<sup>a</sup> Lucentis [NV]

▪ **RANIBIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**

- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe**

10138N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1149.44	38.80	<sup>a</sup> Lucentis [NV]

▪ **RANIBIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
 Department of Human Services

Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

1382R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1149.44	38.80	<sup>a</sup> Lucentis [NV]

▪ **VERTEPORFIN**

**Note** The Department of Human Services should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be predominantly classic (greater than or equal to 50%).

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a baseline visual acuity equal to or better than 6/60 (20/200).

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
  - b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
  - c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).
- A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

**Note** Written applications for authority to prescribe should be forwarded to:  
Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)  
Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- Patient must have been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.
- The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- (a) a completed authority prescription form; and
  - (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form, which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and
  - (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).
- A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**verteporfin 15 mg injection, 1 vial**

1349B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2142.00	38.80	Visudyne [NV]

**OTHER OPHTHALMOLOGICALS**

*Other ophthalmologicals*

▪ **CARBOMER-974**

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-974 0.3% eye gel, 30 x 500 mg unit doses**

5502N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*35.56	36.77	Poly Gel [NV]

**carbomer-974 0.3% eye gel, 30 x 500 mg unit doses**

8514D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*35.56	36.77	Poly Gel [NV]

▪ **CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carbomer-980 0.2% eye gel, 10 g**

5503P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	13.91	15.12	<sup>a</sup> Optifresh eye gel [PP]	<sup>a</sup> PAA [IA]
			<sup>b</sup> 3.85	17.76	15.12	<sup>a</sup> Viscotears [IV]	

**carbomer-980 0.2% eye gel, 10 g**

8384G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	13.91	15.12	<sup>a</sup> Optifresh eye gel [PP]	<sup>a</sup> PAA [IA]
			<sup>b</sup> 3.85	17.76	15.12	<sup>a</sup> Viscotears [IV]	

▪ **CARBOMER-980**

**Authority required (STREAMLINED)**

6172

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses**

5504Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*36.88	38.09	Viscotears Gel PF [IV]

**carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses**

8578L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*36.88	38.09	Viscotears Gel PF [IV]

▪ **CARBOMER-980**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for repeats will be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carbomer-980 0.2% eye gel, 10 g**

9210R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	11	..	13.91	15.12	<sup>a</sup> Optifresh eye gel [PP]	<sup>a</sup> PAA [IA]
			<sup>b</sup> 3.85	17.76	15.12	<sup>a</sup> Viscotears [IV]	

▪ **CARMELLOSE SODIUM**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

5507W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.54	15.75	Refresh Tears Plus [AG]

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

5508X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.54	15.75	Refresh Liquigel [AG]

▪ **CARMELLOSE SODIUM**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

8548X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.54	15.75	Refresh Tears Plus [AG]

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

8593G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.54	15.75	Refresh Liquigel [AG]

▪ **CARMELLOSE SODIUM**

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

2324H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*31.63	32.84	<sup>a</sup> Optifresh Plus [PP]
			<sup>B</sup> 7.29	*38.92	32.84	<sup>a</sup> Celluvisc [AG]

**carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

5505R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*31.63	32.84	<sup>a</sup> Optifresh Plus [PP]
			<sup>B</sup> 7.29	*38.92	32.84	<sup>a</sup> Celluvisc [AG]

**carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses**

5509Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	4	5	..	*39.19	38.80	TheraTears [CX]

**carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses**

8823J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*39.19	38.80	TheraTears [CX]

**carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

2338C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*31.63	32.84	<sup>a</sup> Optifresh Tears [PP]
			<sup>B</sup> 7.29	*38.92	32.84	<sup>a</sup> Cellufresh [AG]

**carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

5506T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*31.63	32.84	<sup>a</sup> Optifresh Tears [PP]
			<sup>B</sup> 7.29	*38.92	32.84	<sup>a</sup> Cellufresh [AG]

**carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses**

5510B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*33.94	35.15	TheraTears [CX]

**carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses**

8824K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*33.94	35.15	TheraTears [CX]

▪ **CARMELLOSE SODIUM**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

9211T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.54	15.75	Refresh Tears Plus [AG]

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

9212W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.54	15.75	Refresh Liquigel [AG]

▪ **CARMELLOSE SODIUM + GLYCEROL**

**Note** The in-use shelf life of Optive is 6 months from the date of opening.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

5556K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	3	..	14.54	15.75	Optive [AG]

▪ **CARMELLOSE SODIUM + GLYCEROL**

**Note** The in-use shelf life of Optive is 6 months from the date of opening.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

9355J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	14.54	15.75	Optive [AG]

▪ **CARMELLOSE SODIUM + GLYCEROL**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The in-use shelf life of Optive is 6 months from the date of opening.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

9356K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	7	..	14.54	15.75	Optive [AG]

▪ **DEXTRAN-70 + HYPROMELLOSE**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

1509K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.63	15.84	<sup>a</sup> Poly-Tears [NM]
			<sup>B</sup> 3.65	18.28	15.84	<sup>a</sup> Tears Naturale [NV]

▪ **DEXTRAN-70 + HYPROMELLOSE**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

5520M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.63	15.84	<sup>a</sup> Poly-Tears [NM]
			<sup>B</sup> 3.65	18.28	15.84	<sup>a</sup> Tears Naturale [NV]

▪ **DEXTRAN-70 + HYPROMELLOSE**

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses**

5521N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*35.98	37.19	Bion Tears [NV]

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses**

8299T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*35.98	37.19	Bion Tears [NV]

▪ **DEXTRAN-70 + HYPROMELLOSE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

9216C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.63	15.84	<sup>a</sup> Poly-Tears [NM]
			<sup>B</sup> 3.65	18.28	15.84	<sup>a</sup> Tears Naturale [NV]

▪ **HYPROMELLOSE**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

2956N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	14.44	15.65	Methopt [QA]

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

8287E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	14.44	15.65	<sup>a</sup> In a Wink Moisturising [NM]
			<sup>B</sup> 4.34	18.78	15.65	<sup>a</sup> Genteal [NV]

▪ **HYPROMELLOSE**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

5517J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	14.44	15.65	Methopt [QA]

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

5518K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	14.44	15.65	<sup>a</sup> In a Wink Moisturising [NM]
			<sup>B</sup> 4.34	18.78	15.65	<sup>a</sup> Genteal [NV]

▪ **HYPROMELLOSE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

9214Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.44	15.65	Methopt [QA]

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

9213X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.44	15.65	<sup>a</sup> In a Wink Moisturising [NM]
			<sup>B</sup> 4.34	18.78	15.65	<sup>a</sup> Genteal [NV]

▪ **HYPROMELLOSE + CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

5519L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	14.44	15.65	<sup>a</sup> HPMC PAA [NM]
			<sup>B</sup> 4.34	18.78	15.65	<sup>a</sup> Genteal gel [NV]

▪ **HYPROMELLOSE + CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

8564R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.44	15.65	<sup>a</sup> HPMC PAA [NM]
			<sup>b</sup> 4.34	18.78	15.65	<sup>a</sup> Genteal gel [NV]

▪ **HYPROMELLOSE + CARBOMER-980**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

9215B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.44	15.65	<sup>a</sup> HPMC PAA [NM]
			<sup>b</sup> 4.34	18.78	15.65	<sup>a</sup> Genteal gel [NV]

▪ **OCRIPLASMIN**

**Note** Where authority approval for treatment for both eyes simultaneously is being sought, a maximum quantity of 2 vials may be requested.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Vitreomacular traction syndrome

**Clinical criteria:**

- Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH); OR
- Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography, **AND**
- The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres, **AND**
- Patient must not have an epiretinal membrane attached to the vitreomacular traction, **AND**
- The condition must be previously untreated in the eye proposed for treatment, **AND**
- Patient must not have received prior vitrectomy in the eye proposed for treatment, **AND**
- Patient must be symptomatic.

**Treatment criteria:**

- Must be treated by an ophthalmologist.
- The prescriber must state which eye(s) is being treated at the time of application.

**ocriplasmin 500 microgram/0.2 mL injection, 0.2 mL vial**

10947E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4149.52	38.80	Jetrea [NV]

▪ **PARAFFIN**

**paraffin 1 g/g eye ointment, 3.5 g**

1754H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*23.97	25.18	Poly Visc [NV]

**paraffin 1 g/g eye ointment, 3.5 g**

5523Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*23.97	25.18	Poly Visc [NV]

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

1750D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	23.42	24.63	Poly Visc [NV]
			<sup>a</sup> 1rcal [PE]			
			<sup>b</sup> 1.84	25.26	24.63	<sup>a</sup> Refresh Night Time [AG]

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

5522P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	23.42	24.63	Poly Visc [NV]

			<sup>a</sup> Ircal [PE]
<sup>B</sup> 1.84	25.26	24.63	<sup>a</sup> Refresh Night Time [AG]

▪ **PARAFFIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

9218E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	23.42	24.63	Poly Visc [NV]
			<sup>B</sup> 1.84	25.26	24.63	<sup>a</sup> Ircal [PE] <sup>a</sup> Refresh Night Time [AG]

▪ **PARAFFIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**paraffin 1 g/g eye ointment, 3.5 g**

9217D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*23.97	25.18	Poly Visc [NV]

▪ **PARAFFIN**

**Note** The in-use shelf life of VitA-POS is 6 months from the date of opening.

**paraffin + retinol palmitate 0.0138% eye ointment, 5 g**

2167C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	2	5	..	*23.97	25.18	VitA-POS [AE]

**paraffin + retinol palmitate 0.0138% eye ointment, 5 g**

2222Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*23.97	25.18	VitA-POS [AE]

▪ **PARAFFIN**

**Note** The in-use shelf life of VitA-POS is 6 months from the date of opening.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**paraffin + retinol palmitate 0.0138% eye ointment, 5 g**

2202X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*23.97	25.18	VitA-POS [AE]

▪ **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

5524R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	14.54	15.75	Systane [NV]

▪ **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

8676P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	14.54	15.75	Systane [NV]

▪ **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

5532E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*33.95	35.16	Systane [NV]

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

9170P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*33.95	35.16	Systane [NV]

▪ **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

9219F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.54	15.75	Systane [NV]

▪ **POLYVINYL ALCOHOL**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyvinyl alcohol 3% eye drops, 15 mL**

8832W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.44	15.65	Vistil Forte [AE]

**polyvinyl alcohol 1.4% eye drops, 15 mL**

2682E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.44	15.65	<sup>a</sup> PVA Tears [PE]
			<sup>b</sup> 1.39	15.83	15.65	<sup>a</sup> Liquifilm Tears [AG]

**polyvinyl alcohol 1.4% eye drops, 15 mL**

8831T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.44	15.65	Vistil [AE]

▪ **POLYVINYL ALCOHOL**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyvinyl alcohol 3% eye drops, 15 mL**

5528Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.44	15.65	Vistil Forte [AE]

**polyvinyl alcohol 1.4% eye drops, 15 mL**

5526W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.44	15.65	<sup>a</sup> PVA Tears [PE]
			<sup>b</sup> 1.39	15.83	15.65	<sup>a</sup> Liquifilm Tears [AG]

**polyvinyl alcohol 1.4% eye drops, 15 mL**

5527X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.44	15.65	Vistil [AE]

▪ **POLYVINYL ALCOHOL**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**polyvinyl alcohol 3% eye drops, 15 mL**

9223K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.44	15.65	Vistil Forte [AE]

**polyvinyl alcohol 1.4% eye drops, 15 mL**

9220G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.44	15.65	<sup>a</sup> PVA Tears [PE]
			<sup>b</sup> 1.39	15.83	15.65	<sup>a</sup> Liquifilm Tears [AG]

**polyvinyl alcohol 1.4% eye drops, 15 mL**

9221H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.44	15.65	Vistil [AE]

▪ **SODIUM HYALURONATE**

**Note** The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

**Authority required (STREAMLINED)**

**4105**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL**

2181T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	34.74	35.95	Hylo-Fresh [AE]

**sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL**

2184Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	34.74	35.95	Hylo-Fresh [AE]

**sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL**

2171G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	‡1	5	..	34.74	35.95	Hylo-Forte [AE]

**sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL**

2253N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	34.74	35.95	Hylo-Forte [AE]

▪ **SOY LECITHIN + TOCOPHEROL + VITAMIN A**

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations**

5545W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	2	5	..	*35.59	36.80	tearsagain [RB]

**soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations**

9448G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*35.59	36.80	tearsagain [RB]

▪ **OTOLOGICALS**

**ANTIINFECTIVES**

*Antiinfectives*

▪ **CIPROFLOXACIN**

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person, **AND**
- Patient must be aged 1 month or older.

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have perforation of the tympanic membrane.

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have a grommet in situ.

**ciprofloxacin 0.3% ear drops, 5 mL**

2480M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	22.27	23.48	Ciloxan [NV]

**CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION**

*Corticosteroids and antiinfectives in combination*

▪ **FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE**

**framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL**

2781J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	14.15	15.36	<sup>a</sup> Otodex [AV]
			<sup>B</sup> 1.66	15.81	15.36	<sup>a</sup> Sofradex [SW]

▪ **TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN**

**triamcinolone acetone 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL**

2971J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	15.15	16.36	<sup>a</sup> Otocomb Otic [FM]
			<sup>B</sup> 1.70	16.85	16.36	<sup>a</sup> Kenacomb Otic [QA]

**triamcinolone acetone 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g**

2974M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	12.62	13.83	<sup>a</sup> Otocomb Otic [FM]
			<sup>B</sup> 1.70	14.32	13.83	<sup>a</sup> Kenacomb Otic [QA]

▪ **OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS**

**ANTIINFECTIVES**

*Antiinfectives*

▪ **FRAMYCETIN SULFATE**

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

1440T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	‡1	2	..	14.67	15.88	Soframycin [SW]

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

5557L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	2	..	14.67	15.88	Soframycin [SW]

▪ **VARIOUS**

▪ **ALLERGENS**

**ALLERGENS**

*Allergen extracts*

## ▪ HONEY BEE VENOM

### bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10621B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	264.51	38.80	Hymenoptera Honey Bee Venom [DE]

### bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2886X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	264.51	38.80	Albey Bee Venom [DE]

## ▪ PAPER WASP VENOM

**Note** Paper wasp venom is not European wasp venom

### paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2918N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	264.51	38.80	Albey Paper Wasp Venom [DE]

## ▪ VESPUULA SPP VENOM

### vespula spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2883R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	264.51	38.80	Albey Yellow Jacket Venom [DE]

## ▪ ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

#### Antidotes

## ▪ NALOXONE

### naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10783M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	82.48	38.80	<sup>a</sup> Naloxone Hydrochloride (DBL) [PF]	<sup>a</sup> Naloxone Juno [JU]

### naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10787R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	82.48	38.80	<sup>a</sup> Naloxone Hydrochloride (DBL) [PF]	<sup>a</sup> Naloxone Juno [JU]

### naloxone hydrochloride 1 mg/ mL injection, 1 x 2 mL syringe

11077B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	74.05	38.80	Prenoxad [PL]

### naloxone hydrochloride 1 mg/ mL injection, 1 x 2 mL syringe

11078C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	74.05	38.80	Prenoxad [PL]

#### Drugs for treatment of hyperkalemia and hyperphosphatemia

## ▪ LANTHANUM

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**5491**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

#### Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**

- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**

9405B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	475.25	38.80	Fosrenol [ZI]

**LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**

9403X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	281.53	38.80	Fosrenol [ZI]

**LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**

9404Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	422.68	38.80	Fosrenol [ZI]

**SEVELAMER****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5491**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer hydrochloride 800 mg tablet, 180**

2142R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	332.52	38.80	Renagel [GZ]

**SUCROFERRIC OXYHYDROXIDE****Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5491**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90**

10250L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	424.03	38.80	Velphoro [FN]

**Detoxifying agents for antineoplastic treatment****FOLINIC ACID****folinic acid 300 mg/30 mL injection, 30 mL vial**

9041W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	1	..	*56.39	38.80	<sup>a</sup> Calcium Folate Ebewe [SZ]	<sup>a</sup> Leucovorin Calcium (Hospira Pty Limited) [PF]

**folinic acid 1 g/100 mL injection, 100 mL vial**

8969C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	49.78	38.80	Calcium Folate Ebewe [SZ]

**▪ FOLINIC ACID**

**Note** For item codes 8740B and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

**folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules**

1610R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	52.92	38.80	<sup>a</sup> Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

**folinic acid 50 mg/5 mL injection, 5 mL vial**

8740B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	2	..	*52.85	38.80	<sup>a</sup> Leucovorin Calcium (Hospira Pty Limited) [PF]

**▪ FOLINIC ACID**

**Note** For item codes 8812T and 1704Q, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

**folinic acid 100 mg/10 mL injection, 10 mL vial**

8812T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*58.15	38.80	<sup>a</sup> Calcium Folate Ebewe [SZ]

**folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules**

1704Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	58.18	38.80	<sup>a</sup> Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

**▪ FOLINIC ACID****Restricted benefit**

Megaloblastic anaemias

**Clinical criteria:**

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

**folinic acid 15 mg tablet, 10**

2308L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	92.81	38.80	Leucovorin Calcium (Hospira Pty Limited) [PF]

**▪ MESNA****Restricted benefit**

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

**Clinical criteria:**

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

**mesna 400 mg/4 mL injection, 15 x 4 mL ampoules**

8078E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	94.74	38.80	Uromitexan [BX]

**mesna 1 g/10 mL injection, 15 x 10 mL ampoules**

8079F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	200.84	38.80	Uromitexan [BX]

***Drugs for treatment of hypercalcemia*****▪ PHOSPHORUS****Authority required (STREAMLINED)****5089**

Hypophosphataemic rickets

**Authority required (STREAMLINED)****5114**

Vitamin D-resistant rickets

**Authority required (STREAMLINED)****5095**

Familial hypophosphataemia

**Authority required (STREAMLINED)**

5123

Hypercalcaemia

**phosphorus 500 mg effervescent tablet, 100**

2946C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	76.04	38.80	Phosphate Sandoz [PL]

**Other therapeutic products****■ POLYLACTIC ACID****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).**Authority required**

Severe facial lipoatrophy

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**polylactic acid 150 mg injection, 1 vial**

9475Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	4	..	*419.77	38.80	Sculptra [GA]

**■ POLYLACTIC ACID****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).**Authority required**

Severe facial lipoatrophy

Treatment Phase: Maintenance PBS-subsidised treatment

**Clinical criteria:**

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**polylactic acid 150 mg injection, 1 vial**

9476R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*419.77	38.80	Sculptra [GA]

**■ DIAGNOSTIC AGENTS****URINE TESTS****■ GLUCOSE AND KETONE INDICATOR URINE****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**glucose and ketone indicator urine diagnostic strip, 50**

3107M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*20.19	21.40	Keto-Diastix [BN]

**■ GLUCOSE INDICATOR URINE****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**glucose indicator urine diagnostic strip, 50**

3104J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*22.17	23.38	Diastix [BN]

## GENERAL NUTRIENTS

### OTHER NUTRIENTS

#### MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

##### Authority required (STREAMLINED)

**6147**

Ketogenic diet

##### **Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

##### Authority required (STREAMLINED)

**6191**

Dietary management of conditions requiring a source of medium chain triglycerides

##### **Clinical criteria:**

- Patient must have chylous ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinaemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

#### triglycerides medium chain oral liquid, 18 x 250 mL cartons

10049X

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*357.87	38.80	betaquik [VF]

#### MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

##### Authority required (STREAMLINED)

**6181**

Chylous ascites

##### Authority required (STREAMLINED)

**6134**

Chylothorax

##### Authority required (STREAMLINED)

**6164**

Fat malabsorption

##### **Clinical criteria:**

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

##### Authority required (STREAMLINED)

**6203**

Hyperlipoproteinaemia type 1

##### Authority required (STREAMLINED)

**6155**

Intractable childhood epilepsy

##### **Clinical criteria:**

- Patient must require a ketogenic diet.

##### Authority required (STREAMLINED)

**6135**

Cerebrospinal fluid glucose transporter defect

##### **Clinical criteria:**

- Patient must require a ketogenic diet.

##### Authority required (STREAMLINED)

**6146**

Long chain fatty acid oxidation disorders

**medium chain triglycerides oral liquid, 250 mL bottle**

9327X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*191.63	38.80	Liquigen [SB]

**medium chain triglycerides oral oil, 500 mL**

3128P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*50.49	38.80	MCT Oil [SB]

**■ PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Population criteria:**

- Patient must be aged from 1 to 10 years inclusive.

**protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 8 x 500 mL pouches**

11110R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*1502.65	38.80	Nutrini Peptisorb Energy [NU]

**■ TRIGLYCERIDES LONG CHAIN**

**Note** Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**triglycerides long chain oral liquid, 18 x 250 mL cartons**

10037G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*289.83	38.80	carbzero [VF]

***Fat/carbohydrates/proteins/minerals/vitamins, combinations*****■ AMINO ACID SYNTHETIC FORMULA**

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula powder for oral liquid, 400 g**

1521C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*501.43	38.80	Neocate Advance Vanilla [SB]

**amino acid synthetic formula powder for oral liquid, 400 g**

2250K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*501.43	38.80	EleCare [AB]

**■ AMINO ACID SYNTHETIC FORMULA**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.  
The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula powder for oral liquid, 400 g**

1180D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*335.87	38.80	Neocate Advance Vanilla [SB]

**amino acid synthetic formula powder for oral liquid, 400 g**

8574G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*335.87	38.80	EleCare [AB]

**amino acid synthetic formula powder for oral liquid, 400 g**

8754R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*335.87	38.80	Neocate Advance [SB]

**■ AMINO ACID SYNTHETIC FORMULA**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.  
Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.  
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.  
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.  
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.  
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula powder for oral liquid, 400 g**

1192R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*335.87	38.80	Neocate Advance Vanilla [SB]

**amino acid synthetic formula powder for oral liquid, 400 g**

8575H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*335.87	38.80	EleCare [AB]

**amino acid synthetic formula powder for oral liquid, 400 g**

8755T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*335.87	38.80	Neocate Advance [SB]

**■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

2246F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*342.43	38.80	Neocate LCP [SB]

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

9339M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*342.43	38.80	EleCare LCP [AB]

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2560R	8	5	..	*342.43	38.80	Neocate LCP [SB]

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9340N	8	5	..	*342.43	38.80	EleCare LCP [AB]

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

1545H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	12	5	..	*511.27	38.80	Neocate Gold [SB]

**■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

5466Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*342.43	38.80	Neocate Gold [SB]

## ■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### **Authority required**

Cows' milk anaphylaxis

### **Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

### **Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

### **Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

### **Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Severe intestinal malabsorption including short bowel syndrome

### **Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

5467R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*342.43	38.80	Neocate Gold [SB]

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

2900P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*342.43	38.80	Alfamino [NT]

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.  
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.  
Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

2928D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*342.43	38.80	Alfamino [NT]

▪ **PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6174**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

**6193**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**

- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)****6204**

Cows' milk protein enteropathy and intolerance to soy protein

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)****6137**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)****6182**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)****6194**

Biliary atresia

**Authority required (STREAMLINED)****6157**

Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)****6205**

Chylous ascites

**Authority required (STREAMLINED)****6195**

Cystic fibrosis

**Authority required (STREAMLINED)****6158**

Enterokinase deficiency

**Authority required (STREAMLINED)****6166**

Proven fat malabsorption

**Authority required (STREAMLINED)****6148**

Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**

- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)****6138**

Severe intestinal malabsorption including short bowel syndrome

**protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 450 g**

8259Q

Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*100.35	38.80	Aptamil Gold+ Pepti-Junior [NU]

NP

## ▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required (STREAMLINED)**

#### **6174**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

#### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

#### **Population criteria:**

- Patient must be up to the age of 24 months.

### **Authority required (STREAMLINED)**

#### **6193**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

#### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

#### **Population criteria:**

- Patient must be up to the age of 24 months.

### **Authority required (STREAMLINED)**

#### **6204**

Cows' milk protein enteropathy and intolerance to soy protein

#### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

#### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

#### **Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

### **Authority required (STREAMLINED)**

#### **6137**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

#### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

#### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

### **Authority required (STREAMLINED)**

#### **6182**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

#### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

### **Authority required (STREAMLINED)**

#### **6194**

Biliary atresia

### **Authority required (STREAMLINED)**

#### **6157**

Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

**6205**

Chylous ascites

**Authority required (STREAMLINED)**

**6195**

Cystic fibrosis

**Authority required (STREAMLINED)**

**6158**

Enterokinase deficiency

**Authority required (STREAMLINED)**

**6166**

Proven fat malabsorption

**Authority required (STREAMLINED)**

**6148**

Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**

- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**

**6138**

Severe intestinal malabsorption including short bowel syndrome

**Authority required (STREAMLINED)**

**6206**

Chylothorax

### protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 400 g

2676W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*154.03	38.80	Alfaré [NT]

### ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

#### **Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

#### **Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

### triglycerides medium chain formula powder for oral liquid, 400 g

10152H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*394.99	38.80	Monogen [SB]

### triglycerides medium chain formula powder for oral liquid, 400 g

10155L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*416.11	38.80	Lipistart [VF]

### triglycerides medium chain formula oral liquid, 8 x 500 mL pouches

10375C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*824.43	38.80	Nutrini Peptisorb [SB]

### ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

#### **Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

#### **Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula powder for oral liquid, 400 g**

10154K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*385.31	38.80	Peptamen Junior [NT]

**▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Hyperlipoproteinaemia type 1

**Restricted benefit**

Long chain fatty acid oxidation disorders

**Restricted benefit**

Chylous ascites

**Restricted benefit**

Chylothorax

**triglycerides medium chain formula powder for oral liquid, 400 g**

1938B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*416.11	38.80	Lipistart [VF]

**triglycerides medium chain formula powder for oral liquid, 400 g**

8478F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*394.99	38.80	Monogen [SB]

***Carbohydrates*****▪ MODIFIED LONG CHAIN AMYLOPECTIN****Restricted benefit**

Glycogen storage disease

**modified long chain amylopectin powder for oral liquid, 30 x 60 g sachets**

9386B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*709.95	38.80	Glycosade [VF]

***Amino acids/carbohydrates/minerals/vitamins, combinations*****▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES****Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

#### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

#### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

#### **Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

#### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

#### **Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

#### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

#### **Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

#### **Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

#### **Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

- Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### **amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral liquid: powder for, 400 g**

10522T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*353.31	38.80	Alfamino Junior [NT]

### **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

#### **Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

#### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**

- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides  
oral liquid: powder for, 400 g

10527C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*353.31	38.80	Alfamino Junior [NT]

#### ■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

##### Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

##### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

##### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

##### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

##### Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

##### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

##### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

##### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

##### Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

##### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

##### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

##### **Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

##### Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

##### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

##### **Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

##### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

##### Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

11161K

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*353.31	38.80	Neocate Junior [SB]

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

11183N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*353.31	38.80	Neocate Junior [SB]

*Milk substitutes*

▪ **MILK POWDER LACTOSE FREE FORMULA**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No more than 1 application per patient will be authorised.

**Authority required**

Acute lactose intolerance

**Population criteria:**

- Patient must be up to the age of 12 months.
- The date of birth of the patient must be included in the authority application.

**milk powder lactose free formula powder for oral liquid, 900 g**

8282X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	..	..	*103.05	38.80	S-26 LF [AS]

▪ **MILK POWDER LACTOSE FREE FORMULA PREDIGESTED**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No more than 1 application per patient will be authorised.

**Authority required**

Acute lactose intolerance

**Population criteria:**

- Patient must be up to the age of 12 months.
- The date of birth of the patient must be provided at the time of application.

**milk powder lactose free formula predigested powder for oral liquid, 900 g**

2975N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	..	..	*88.00	38.80	Aptamil Gold+ De-Lact [NU]

**▪ MILK POWDER LACTOSE INTOLERANCE FORMULA**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No more than 1 application per patient will be authorised.

**Authority required**

Acute lactose intolerance

**Population criteria:**

- Patient must be up to the age of 12 months.
- The date of birth of the patient must be provided at the time of application.

**milk powder lactose intolerance formula powder for oral liquid, 900 g**

11209Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	..	..	*103.05	38.80	S-26 Original LI [AS]

**▪ MILK POWDER SYNTHETIC LOW CALCIUM**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Hypercalcaemia

**Population criteria:**

- Patient must be under the age of 4 years.

**milk powder synthetic low calcium powder for oral liquid, 400 g**

3092R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*355.87	38.80	Locasol [SB]

***Other combinations of nutrients*****▪ AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE****Restricted benefit**

Phenylketonuria

**amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 20 g sachets**

10806R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1000.43	38.80	PKU Go [OH]

**▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE****Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g**

10683G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	7	5	..	*1929.63	38.80	PKU Easy Microtabs [OH]

**▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID****Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine and supplemented with docosahexaenoic acid oral liquid, 20 x 500 mL bottles**

10822N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*633.75	38.80	PKU Baby [OH]

**▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID****Restricted benefit**

Pyridoxine non-responsive homocystinuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans

3417W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2393.07	38.80	HCU Anamix junior LQ [SB]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE**

Restricted benefit

Phenylketonuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles

10632N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*1905.85	38.80	PKU Easy Shake & Go [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE**

Restricted benefit

Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine oral liquid: powder for, 30 x 34 g bottles

10934L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2953.95	38.80	TYR Easy Shake & Go [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

Restricted benefit

Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans

9330C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2393.07	38.80	TYR Anamix junior LQ [SB]

■ **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 18 g sachets

10715Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2012.19	38.80	GA1 Anamix Junior [NU]

■ **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 25 g sachets

5484P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3007.19	38.80	GA express 15 [VF]

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 24 g sachets

9438R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2012.23	38.80	GA gel [VF]

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 400 g

2650L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*726.03	38.80	GA1 Anamix infant [SB]

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10466Q NP	9	5	..	*2935.75	38.80	XLYS, LOW TRY Maxamum [SB]

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE****Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2640Y NP	4	5	..	*3888.75	38.80	HCU cooler 20 [VF]

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 25 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8744F NP	4	5	..	*2953.95	38.80	HCU express 15 [VF]

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9133Q NP	4	5	..	*2953.95	38.80	HCU cooler 15 [VF]

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 24 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8677Q NP	4	5	..	*2012.23	38.80	HCU gel [VF]

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 500 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8416Y NP	8	5	..	*2579.95	38.80	XMET Maxamum [SB]

**AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1548L NP	3	5	..	*2953.90	38.80	HCU Lophlex LQ 20 [SB]

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2639X NP	4	5	..	*2012.23	38.80	HCU cooler 10 [VF]

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE****Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10693T NP	4	5	..	*2012.23	38.80	HCU Anamix Junior [NU]

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE****Restricted benefit**

Pyridoxine non-responsive homocystinuria

**Population criteria:**

- Patient must be an infant or a very young child.

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 400 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8417B NP	8	5	..	*726.03	38.80	HCU Anamix infant [SB]

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE****Restricted benefit**

Methylmalonic acidaemia

**Restricted benefit**

Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 25 g sachets**

3443F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2953.95	38.80	MMA/PA express 15 [VF]

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 500 g**

8061G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2579.95	38.80	XMTVI Maxamum [SB]

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 24 g sachets**

3444G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2012.23	38.80	MMA/PA gel [VF]

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 400 g**

8058D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*726.03	38.80	MMA/PA Anamix infant [SB]

**AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1**

1923F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2953.95	38.80	MMA/PA cooler 15 [VF]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE****Restricted benefit**

Methylmalonic acidaemia

**Restricted benefit**

Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 18 g sachets**

10730R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2012.19	38.80	MMA/PA Anamix Junior [NU]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE****Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 24 g sachets**

8555G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1000.43	38.80	PKU gel [VF]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans**

2382J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*976.99	38.80	PKU Cooler 10 [VF]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouch**

10411Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1952.87	38.80	PKU Air 20 [VF]

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 27.8 g sachets**

8804J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1930.63	38.80	PKU Lophlex [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL**

8746H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*1243.95	38.80	Easiphen [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9396M NP	4	5	..	*1202.91	38.80	PKU Anamix Junior LQ [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9021T NP	4	5	..	*1930.63	38.80	PKU Lophlex LQ 20 [SB]

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 50 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8727H NP	3	5	..	*1431.91	38.80	XP Maxamum [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8846N NP	4	5	..	*1466.15	38.80	PKU Cooler 15 [VF]

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2738D NP	8	5	..	*834.51	38.80	XP Maxamaid [SB]

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2739E NP	8	5	..	*1280.99	38.80	XP Maxamum [SB]

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1909L NP	4	5	..	*1952.87	38.80	PKU express 20 [VF]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9397N NP	2	5	..	*1001.21	38.80	PKU Lophlex LQ 10 [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2806Q NP	3	5	..	*1754.98	38.80	PKU Lophlex Sensation 20 [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouch**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10410X NP	4	5	..	*1466.15	38.80	PKU Air 15 [VF]

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 25 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8591E NP	4	5	..	*1466.95	38.80	PKU express 15 [VF]

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1411G NP	3	5	..	*1552.93	38.80	add-ins [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2474F NP	4	5	..	*1952.87	38.80	PKU Cooler 20 [VF]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5483N NP	4	5	..	*1000.43	38.80	PKU squeeze [VF]

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE**

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets**

10258X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1001.63	38.80	PKU Anamix Junior [SB]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE****Restricted benefit**

Tyrosinaemia

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1**

1547K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*2953.90	38.80	TYR Lophlex LQ 20 [SB]

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 25 g sachets**

8667E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2953.95	38.80	TYR express 15 [VF]

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL sachets**

2701E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3888.75	38.80	TYR cooler 20 [VF]

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 24 g sachets**

8631G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2012.23	38.80	TYR gel [VF]

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans**

9132P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2953.95	38.80	TYR cooler 15 [VF]

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g sachets**

11151X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3888.75	38.80	TYR express 20 [VF]

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 500 g**

3078B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2579.95	38.80	XPhen, Tyr Maxamum [SB]

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 400 g**

8445L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*726.03	38.80	TYR Anamix infant [SB]

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL sachets**

2674R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2012.23	38.80	TYR cooler 10 [VF]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE****Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.**Restricted benefit**

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets**

10260B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2012.23	38.80	TYR Anamix Junior [SB]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE****Restricted benefit**

Maple syrup urine disease

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1**

1914R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3899.91	38.80	MSUD express 20 [VF]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans**

2375B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2953.95	38.80	MSUD cooler 15 [VF]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches**

2654Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3888.75	38.80	MSUD cooler 20 [VF]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 25 g sachets**

8632H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2953.95	38.80	MSUD express 15 [VF]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 24 g sachets**

8592F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2012.23	38.80	MSUD gel [VF]

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1**

1546J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*2953.90	38.80	MSUD Lophlex LQ 20 [SB]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches**

2651M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2012.23	38.80	MSUD cooler 10 [VF]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g**

8057C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2579.95	38.80	MSUD Maxamum [SB]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g**

8310J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2548.87	38.80	MSUD AID III [SB]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 400 g**

2380G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*726.03	38.80	MSUD Anamix infant [SB]

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE**

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 36 g sachets**

10259Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2012.23	38.80	MSUD Anamix Junior [SB]

▪ **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9499Y	4	5	..	*2393.07	38.80	MSUD Anamix Junior LQ [SB]

NP

▪ **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID**

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11185Q	8	5	..	*1000.35	38.80	PKU Anamix First Spoon [SB]

NP

▪ **AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8479G	8	5	..	*663.95	38.80	PKU Anamix infant [SB]

NP

▪ **AMINO ACID FORMULA WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**amino acid formula without phenylalanine 500 mg capsule, 200**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8554F	16	5	..	*1209.07	38.80	Phlexy-10 [SB]

NP

**amino acid formula without phenylalanine powder for oral liquid, 30 x 20 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2347M	7	5	..	*1385.45	38.80	Phlexy-10 Drink Mix [SB]

NP

**amino acid formula without phenylalanine 1 g tablet, 75**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8678R	24	5	..	*1351.39	38.80	Phlexy-10 [SB]

NP

▪ **AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE**

**Restricted benefit**

Maple syrup urine disease

**amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent oral liquid: powder for, 30 x 6 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10161T	12	5	..	*3101.59	38.80	MSUD amino5 [VF]

NP

▪ **ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**

**Restricted benefit**

Peroxisomal biogenesis disorders

**arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10036F	4	5	..	*363.31	38.80	keyomega [VF]

NP

## ■ ARGININE WITH CARBOHYDRATE

**Note** Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

### Restricted benefit

Urea cycle disorders

#### arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets

5482M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*727.51	38.80	Arginine 2000 [VF]

#### arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets

9437Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*486.55	38.80	Arginine 500 [VF]

#### arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets

10093F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*966.03	38.80	Arginine 5000 [VF]

## ■ CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS

### Restricted benefit

Proven inborn errors of protein metabolism

#### Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

#### carbohydrate, fat, vitamins, minerals and trace elements powder for oral liquid, 400 g

8369L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*293.63	38.80	Energivit [SB]

## ■ CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

### Restricted benefit

Proven inborn errors of protein metabolism

#### Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

#### carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories powder for oral liquid, 30 x 43 g sachets

10039J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*468.19	38.80	basecal 200 [VF]

#### carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories powder for oral liquid, 30 x 21.5 g sachets

10050Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*236.47	38.80	basecal 100 [VF]

## ■ CITRULLINE

**Note** Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

### Restricted benefit

Urea cycle disorders

#### Clinical criteria:

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

#### citrulline 1 g tablet, 300

10736C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	1197.40	38.80	Citrulline Easy [OH]

## ■ CITRULLINE WITH CARBOHYDRATE

**Note** Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

### Restricted benefit

Urea cycle disorders

#### Clinical criteria:

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

**citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets**

5481L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*486.55	38.80	Citrulline 1000 [VF]

**■ CYSTINE WITH CARBOHYDRATE****Restricted benefit**

Pyridoxine non-responsive homocystinuria

**cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets**

9164H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*486.55	38.80	Cystine 500 [VF]

**■ DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE****Restricted benefit**

Peroxisomal biogenesis disorders

**docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets**

10040K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*363.31	38.80	docomega [VF]

**■ ESSENTIAL AMINO ACIDS FORMULA****Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula powder for oral liquid, 2 x 200 g**

9329B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	6	5	..	*1137.37	38.80	Essential Amino Acid Mix [SB]

**■ ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C****Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g**

2027Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	5	..	*598.30	38.80	Dialamine [SB]

**■ ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS****Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula with vitamins and minerals powder for oral liquid, 50 x 12.5 g sachets**

9385Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1436.07	38.80	EAA Supplement [VF]

**■ GLYCINE WITH CARBOHYDRATE****Restricted benefit**

Isovaleric acidaemia

**glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets**

10195N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*511.95	38.80	Glycine500 [VF]

**■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS****Restricted benefit**

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g**

2644E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	14	5	..	*1288.71	38.80	Camino Pro Complete [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 30 x 49 g sachets**

10652P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1570.63	38.80	Camino Pro Bettermilk [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g**

2696X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	14	5	..	*860.73	38.80	Camino Pro Complete [QH]

**■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS**

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**Restricted benefit**

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g protein oral liquid, 30 x 250 mL cartons**

10359F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1072.79	38.80	PKU Glytactin RTD 10 [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 30 x 250 mL cartons**

10332T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1570.59	38.80	PKU Glytactin RTD 15 [QH]

**■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS****Restricted benefit**

Tyrosinaemia

**glycomacropeptide and essential amino acids with vitamins and minerals 15 g protein equivalent oral liquid, 30 x 250 mL cartons**

10528D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3101.55	38.80	Tylactin RTD [QH]

**■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS****Restricted benefit**

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 51 g sachets**

10992M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2068.43	38.80	PKU Bettermilk Lite [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 g sachets**

11084J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*1311.85	38.80	PKU Restore [QH]

**■ GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACID AND DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE****Restricted benefit**

Phenylketonuria

**glycomacropeptide formula with long chain polyunsaturated fatty acid and docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets**

11071Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2068.43	38.80	PKU Sphere [VF]

**■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

**Note** Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR

- Patient must have pyruvate dehydrogenase deficiency.  
Keyo should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs**

11108P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*866.05	38.80	Keyo [VF]

▪ **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

**Note** Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons**

10185C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	5	..	*931.85	38.80	KetoCal 4:1 LQ [SB]

▪ **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g**

2652N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	24	5	..	*979.63	38.80	KetoCal 3:1 [SB]

▪ **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g**

9446E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	24	5	..	*979.63	38.80	KetoCal 4:1 [SB]

▪ **ISOLEUCINE WITH CARBOHYDRATE**

**Restricted benefit**

Maple syrup urine disease

**isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets**

9436P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*534.75	38.80	Isoleucine 1000 [VF]

**isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets**

9134R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*486.55	38.80	Isoleucine 50 [VF]

**▪ MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE****Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**milk protein and fat formula with vitamins and minerals carbohydrate free powder for oral liquid, 225 g**

8630F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	24	5	..	*611.71	38.80	Carbohydrate Free Mixture [SB]

**▪ PHENYLALANINE WITH CARBOHYDRATE****Restricted benefit**

Tyrosinaemia

**phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets**

9384X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*486.55	38.80	Phenylalanine 50 [VF]

**▪ PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID****Restricted benefit**

Phenylketonuria

**protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches**

10658Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*1904.80	38.80	PKU Easy [OH]

**▪ SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE****Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can**

8577K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	120	5	..	*632.35	38.80	RCF [AB]

**▪ TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER****Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**triglycerides long chain with glucose polymer oral liquid, 6 x 1 L bottles**

9309Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*279.67	38.80	ProZero [VF]

**triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons**

10189G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*171.23	38.80	Sno-Pro [SB]

**triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans**

9308X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*314.83	38.80	ProZero [VF]

## ▪ TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER

### Restricted benefit

Proven inborn errors of protein metabolism

### Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

### triglycerides medium chain and long chain with glucose polymer powder for oral liquid, 400 g

3136C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*271.31	38.80	Duocal [SB]

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

### Authority required (STREAMLINED)

#### **6165**

Chylous ascites

### Authority required (STREAMLINED)

#### **6192**

Chylothorax

### Authority required (STREAMLINED)

#### **6173**

Fat malabsorption

### Clinical criteria:

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

### Authority required (STREAMLINED)

#### **6156**

Hyperlipoproteinaemia type 1

### Authority required (STREAMLINED)

#### **6136**

Long chain fatty acid oxidation disorders

### triglycerides medium chain formula powder for oral liquid, 30 x 16 g sachets

9383W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*230.19	38.80	MCT Pro-Cal [VF]

## ▪ TYROSINE WITH CARBOHYDRATE

### Restricted benefit

Phenylketonuria

### tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets

9165J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*486.55	38.80	Tyrosine 1000 [VF]

## ▪ VALINE WITH CARBOHYDRATE

### Restricted benefit

Maple syrup urine disease

### valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets

9135T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*486.55	38.80	Valine 50 [VF]

### valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets

9434M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*534.75	38.80	Valine 1000 [VF]

## ▪ VITAMINS, MINERALS AND TRACE ELEMENTS FORMULA

**Note** Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician.

### Restricted benefit

Dietary management of conditions requiring a highly restrictive therapeutic diet

### Clinical criteria:

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**

- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**vitamins, minerals and trace elements formula powder for oral liquid, 30 x 7 g sachets**

11200L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	274.69	38.80	Phlexy-Vits [SB]

**■ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**

**Note** FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 6 g sachets**

10149E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	274.69	38.80	FruitiVits [VF]

**■ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**

**Note** Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be an infant or a child.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 200 g**

9328Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*364.57	38.80	Paediatric Seravit [SB]

**■ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE****Authority required (STREAMLINED)****6190**

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans**

2870C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1500.15	38.80	Renastart [VF]

**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 10 x 100 g sachets**

9382T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	9	5	..	*1406.92	38.80	RenaStart [VF]

**■ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE****Authority required (STREAMLINED)**

**6190**

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose powder for oral liquid, 400 g**

8587Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	16	5	..	*1007.95	38.80	Kindergen [SB]

# Palliative Care

ALIMENTARY TRACT AND METABOLISM.....	757
STOMATOLOGICAL PREPARATIONS .....	757
STOMATOLOGICAL PREPARATIONS.....	757
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS.....	757
BELLADONNA AND DERIVATIVES, PLAIN .....	757
PROPULSIVES.....	757
DRUGS FOR CONSTIPATION .....	757
DRUGS FOR CONSTIPATION.....	757
MUSCULO-SKELETAL SYSTEM.....	759
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS.....	759
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON- STEROIDS.....	759
NERVOUS SYSTEM.....	761
ANALGESICS.....	761
OPIOIDS .....	761
OTHER ANALGESICS AND ANTIPYRETICS.....	766
ANTIEPILEPTICS.....	766
ANTIEPILEPTICS .....	766
PSYCHOLEPTICS.....	767
ANXIOLYTICS .....	767
HYPNOTICS AND SEDATIVES .....	767

## ALIMENTARY TRACT AND METABOLISM

### STOMATOLOGICAL PREPARATIONS

#### STOMATOLOGICAL PREPARATIONS

*Other agents for local oral treatment*

#### BENZYDAMINE

**Authority required (STREAMLINED)**

**6197**

Painful mouth

**Clinical criteria:**

- Patient must be receiving palliative care.

**benzydamine hydrochloride 0.15% mouthwash, 500 mL**

5385K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	24.18	25.39	Difflam [IA]

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

#### HYOSCINE BUTYLBROMIDE

**Authority required (STREAMLINED)**

**6207**

For use in patients receiving palliative care

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

5317W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	3	..	*85.15	38.80	<sup>a</sup> Buscopan [VZ]	<sup>a</sup> HYOSCINE BUTYLBROMIDE SXP [XC]

### PROPULSIVES

*Propulsives*

#### METOCLOPRAMIDE

**Authority required (STREAMLINED)**

**6084**

Nausea or gastric stasis

**Clinical criteria:**

- Patient must be receiving palliative care.

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

10762K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	..	..	*33.95	35.16	Maxolon [IA]

## DRUGS FOR CONSTIPATION

### DRUGS FOR CONSTIPATION

*Contact laxatives*

#### BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**bisacodyl 10 mg suppository, 12**

5304E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*21.43	22.64	Petrus Bisacodyl Suppositories [PP]

**bisacodyl 10 mg suppository, 10**

5303D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*23.71	24.92	<sup>a</sup> Petrus Bisacodyl Suppositories [PP]
			<sup>b</sup> 1.29	*25.00	24.92	<sup>a</sup> Dulcolax [VZ]

**bisacodyl 5 mg enteric tablet, 200**

5301B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	17.08	18.29	Lax-Tab [AE]

*Bulk-forming laxatives***■ RHAMNUS FRANGULA + STERCULIA****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

5322D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	27.57	28.78	Normacol Plus [NE]

*Osmotically acting laxatives***■ MACROGOL-3350**

**Note** Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****6170**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

5426N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*26.23	27.44	<sup>a</sup> OsmoLax [KY]

**macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets**

2351R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*26.23	27.44	<sup>a</sup> Herron ClearLax [ON]

**■ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE****Authority required (STREAMLINED)****6171**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets**

5389P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*26.23	27.44	<sup>a</sup> APO-MACROGOL plus ELECTROLYTES [TX] <sup>a</sup> LaxaCon [EA] <sup>a</sup> Macrovic [RF] <sup>a</sup> Movicol [NE]	<sup>a</sup> Chemists' Own Macrogol with Electrolytes [RW] <sup>a</sup> lax-sachets [AE] <sup>a</sup> Molaxole [HM]

**macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL**

10127B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*21.17	22.38	Movicol Liquid [NE]

*Enemas***■ BISACODYL****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**bisacodyl 10 mg/5 mL enema, 25 x 5 mL**

5302C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	38.50	38.80	Bisalax [AS]

▪ **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL**

5331N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*29.35	30.56	Micolette [AE]

*Peripheral opioid receptor antagonists*

▪ **METHYLNALTREXONE**

**Authority required (STREAMLINED)**

**6180**

Opioid-induced constipation

**Clinical criteria:**

- The treatment must be in combination with oral laxatives, **AND**
- Patient must be receiving palliative care, **AND**
- Patient must have failed to respond to laxatives.

**METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7**

5424L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	263.80	38.80	Relistor [LM]

**methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial**

5423K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	7	..	..	*263.77	38.80	Relistor [LM]

▪ **MUSCULO-SKELETAL SYSTEM**

▪ **ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS**

**ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS**

*Acetic acid derivatives and related substances*

▪ **DICLOFENAC**

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**diclofenac sodium 100 mg suppository, 20**

5363G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*27.51	28.72	Voltaren 100 [NV]

**diclofenac sodium 50 mg enteric tablet, 50**

5362F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	3	..	13.14	14.35	<sup>a</sup> APO-Diclofenac [TX]	<sup>a</sup> Clonac 50 [RW]
						<sup>a</sup> Diclofenac Amneal [ED]	<sup>a</sup> Diclofenac AN [EA]
						<sup>a</sup> Diclofenac Sandoz [SZ]	<sup>a</sup> Fenac [AF]
			<sup>b</sup> 3.46	16.60	14.35	<sup>a</sup> Voltaren 50 [NV]	

**diclofenac sodium 25 mg enteric tablet, 50**

5361E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*14.03	15.24	<sup>a</sup> APO-Diclofenac [TX]	<sup>a</sup> Clonac 25 [RW]
						<sup>a</sup> Diclofenac Amneal [ED]	<sup>a</sup> Diclofenac AN [EA]
						<sup>a</sup> Diclofenac Sandoz [SZ]	<sup>a</sup> Fenac 25 [AF]
			<sup>b</sup> 3.44	*17.47	15.24	<sup>a</sup> Voltaren 25 [NV]	

▪ **INDOMETHACIN**

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

# MUSCULO-SKELETAL SYSTEM

## indomethacin 100 mg suppository, 20

5378C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*25.07	26.28	Indocid [AS]

## indomethacin 25 mg capsule, 50

5377B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*16.69	17.90	<sup>a</sup> Arthrexin [AF]
			<sup>B</sup> 4.04	*20.73	17.90	<sup>a</sup> Indocid [AS]

### Propionic acid derivatives

#### ■ IBUPROFEN

##### Restricted benefit

Severe pain

##### Clinical criteria:

- Patient must be receiving palliative care.

## ibuprofen 400 mg tablet, 30

5368M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	3	..	*16.84	18.05	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> Brufen [GO]

#### ■ NAPROXEN

##### Restricted benefit

Severe pain

##### Treatment criteria:

- Patient must be undergoing palliative care.

##### Clinical criteria:

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

## naproxen 125 mg/5 mL oral liquid, 474 mL

5397C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	121.27	38.80	Phebra Naproxen Suspension [PL]

#### ■ NAPROXEN

##### Restricted benefit

Severe pain

##### Clinical criteria:

- Patient must be receiving palliative care.

## naproxen 1 g modified release tablet, 28

5348L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	17.65	18.86	<sup>a</sup> Proxen SR 1000 [IY]
			<sup>B</sup> 1.12	18.77	18.86	<sup>a</sup> Naprosyn SR1000 [IX]

## naproxen 250 mg tablet, 50

5345H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*18.35	19.56	<sup>a</sup> Inza 250 [AF]
			<sup>B</sup> 2.24	*20.59	19.56	<sup>a</sup> Naprosyn [IX]

## naproxen 500 mg tablet, 50

5346J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.46	17.67	<sup>a</sup> Inza 500 [AF]
			<sup>B</sup> 1.12	17.58	17.67	<sup>a</sup> Naprosyn [IX]

## naproxen 750 mg modified release tablet, 28

5347K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.01	17.22	<sup>a</sup> Proxen SR 750 [IY]
			<sup>B</sup> 1.06	17.07	17.22	<sup>a</sup> Naprosyn SR750 [IX]

#### ■ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

##### Restricted benefit

Severe pain

##### Clinical criteria:

- Patient must be receiving palliative care.

**naproxen sodium 550 mg tablet, 50**

5353R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.61	17.82	<sup>a</sup> Crysanal [IY]
			<sup>b</sup> 1.89	18.50	17.82	<sup>a</sup> Anaprox 550 [IX]

■ **NERVOUS SYSTEM**

■ **ANALGESICS**

**OPIOIDS**

*Natural opium alkaloids*

■ **MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 200 mg modified release tablet, 28**

5391R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	116.58	38.80	MS Contin [MF]

■ **MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 20 mg tablet, 20**

5394X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.43	20.64	Sevredol [MF]

**morphine sulfate 10 mg tablet, 20**

5393W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18.61	19.82	Sevredol [MF]

*Phenylpiperidine derivatives*

■ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 600 microgram sublingual tablet, 10**

10604D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.21	38.80	Abstral [FK]

**FENTANYL Lozenges 600 micrograms (as citrate), 9**

5403J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.35	38.80	Actiq [TB]

**FENTANYL Lozenges 400 micrograms (as citrate), 9**

5402H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.35	38.80	Actiq [TB]

**fentanyl 300 microgram sublingual tablet, 10**

10606F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.21	38.80	Abstral [FK]

**FENTANYL Lozenges 200 micrograms (as citrate), 9**

5401G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.35	38.80	Actiq [TB]

**fentanyl 400 microgram sublingual tablet, 10**

10603C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.21	38.80	Abstral [FK]

**FENTANYL Lozenges 1600 micrograms (as citrate), 9**

5406M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.35	38.80	Actiq [TB]

**fentanyl 100 microgram sublingual tablet, 10**

10601Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*160.32	38.80	Abstral [FK]

**FENTANYL Lozenges 800 micrograms (as citrate), 9**

5404K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.35	38.80	Actiq [TB]

**fentanyl 200 microgram sublingual tablet, 10**

10600X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*160.32	38.80	Abstral [FK]

**fentanyl 800 microgram sublingual tablet, 10**

10612M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.21	38.80	Abstral [FK]

**FENTANYL Lozenges 1200 micrograms (as citrate), 9**

5405L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.35	38.80	Actiq [TB]

■ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 400 microgram orally disintegrating tablet, 4**

10739F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*72.60	38.80	Fentora [TB]

**fentanyl 100 microgram orally disintegrating tablet, 4**

10729Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*72.60	38.80	Fentora [TB]

**fentanyl 600 microgram orally disintegrating tablet, 4**

10722H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*72.60	38.80	Fentora [TB]

**fentanyl 200 microgram orally disintegrating tablet, 4**

10697B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*72.60	38.80	Fentora [TB]

**fentanyl 800 microgram orally disintegrating tablet, 4**

10723J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*72.60	38.80	Fentora [TB]

**■ FENTANYL**

**Caution** The risk of drug dependence is high.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 months' therapy.

**Authority required**

Breakthrough pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 300 microgram sublingual tablet, 30**

10610K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*461.84	38.80	Abstral [FK]

**FENTANYL Lozenge 800 micrograms (as citrate), 30**

5410R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.36	38.80	Actiq [TB]

**FENTANYL Lozenge 400 micrograms (as citrate), 30**

5408P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.36	38.80	Actiq [TB]

**fentanyl 400 microgram sublingual tablet, 30**

10608H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*461.84	38.80	Abstral [FK]

**fentanyl 100 microgram sublingual tablet, 30**

10602B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*461.84	38.80	Abstral [FK]

**FENTANYL Lozenge 600 micrograms (as citrate), 30**

5409Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.36	38.80	Actiq [TB]

**FENTANYL Lozenge 200 micrograms (as citrate), 30**

5407N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.36	38.80	Actiq [TB]

**fentanyl 200 microgram sublingual tablet, 30**

10607G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*461.84	38.80	Abstral [FK]

**fentanyl 600 microgram sublingual tablet, 30**

10613N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*461.84	38.80	Abstral [FK]

**fentanyl 800 microgram sublingual tablet, 30**

10611L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*461.84	38.80	Abstral [FK]

**FENTANYL Lozenge 1200 micrograms (as citrate), 30**

5411T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.36	38.80	Actiq [TB]

**FENTANYL Lozenge 1600 micrograms (as citrate), 30**

5412W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.36	38.80	Actiq [TB]

■ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 months' therapy.

**Authority required**

Breakthrough pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 800 microgram orally disintegrating tablet, 28**

10738E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*431.58	38.80	Fentora [TB]

**fentanyl 200 microgram orally disintegrating tablet, 28**

10698C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*431.58	38.80	Fentora [TB]

**fentanyl 400 microgram orally disintegrating tablet, 28**

10737D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*431.58	38.80	Fentora [TB]

**fentanyl 600 microgram orally disintegrating tablet, 28**

10713W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*431.58	38.80	Fentora [TB]

**fentanyl 100 microgram orally disintegrating tablet, 28**

10684H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*431.58	38.80	Fentora [TB]

**Diphenylpropylamine derivatives****■ METHADONE**

**Caution** The risk of drug dependence is high.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 month's therapy.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Chronic severe disabling pain

Treatment Phase: Initial treatment, for up to 3 months

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

5399E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	22.60	23.81	Aspen Methadone Syrup [QA]

**■ METHADONE**

**Caution** The risk of drug dependence is high.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 month's therapy.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Chronic severe disabling pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

5400F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	22.60	23.81	Aspen Methadone Syrup [QA]

**Oripavine derivatives****■ BUPRENORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

# NERVOUS SYSTEM

Palliative

## buprenorphine 15 microgram/hour patch, 2

10953L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*80.56	38.80	Norspan [MF]

## buprenorphine 40 microgram/hour patch, 2

10959T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*148.52	38.80	Norspan [MF]

## buprenorphine 25 microgram/hour patch, 2

10964C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*108.20	38.80	Norspan [MF]

## buprenorphine 10 microgram/hour patch, 2

10948F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*66.38	38.80	Norspan [MF]

## buprenorphine 20 microgram/hour patch, 2

10970J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*94.76	38.80	Norspan [MF]

## buprenorphine 30 microgram/hour patch, 2

10949G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*121.64	38.80	Norspan [MF]

## buprenorphine 5 microgram/hour patch, 2

10957Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*43.14	38.80	Norspan [MF]

## OTHER ANALGESICS AND ANTIPYRETICS

### Anilides

#### PARACETAMOL

##### Restricted benefit

Analgesia or fever

##### Clinical criteria:

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

#### paracetamol 500 mg suppository, 24

5319Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	3	..	*82.07	38.80	Panadol [GC]

#### PARACETAMOL

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

##### Restricted benefit

Analgesia or fever

##### Clinical criteria:

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

#### paracetamol 665 mg tablet: modified release, 192

10796F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	18.55	19.76	<sup>a</sup> Osteomol 665 Paracetamol [CR]

#### paracetamol 665 mg modified release tablet, 96

5343F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*18.55	19.76	<sup>a</sup> APOHEALTH Osteo Relief Paracetamol 665 mg [TX]	<sup>a</sup> Osteomol 665 Paracetamol [CR]

#### ANTIPILEPTICS

### ANTIPILEPTICS

#### Benzodiazepine derivatives

## CLONAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Myoclonus

### Clinical criteria:

- The treatment must be for prophylaxis or prevention of the indication, **AND**
- Patient must be receiving palliative care.

### clonazepam 500 microgram tablet, 100

5337X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.78	17.99	<sup>a</sup> Paxam 0.5 [AF]
			<sup>b</sup> 1.84	18.62	17.99	<sup>a</sup> Rivotril [RO]

### clonazepam 2 mg tablet, 100

5338Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	21.80	23.01	<sup>a</sup> Paxam 2 [AF]
			<sup>b</sup> 2.30	24.10	23.01	<sup>a</sup> Rivotril [RO]

### clonazepam 2.5 mg/mL oral liquid, 10 mL

5339B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*18.59	19.80	Rivotril [RO]

## PSYCHOLEPTICS

### ANXIOLYTICS

#### Benzodiazepine derivatives

## DIAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Anxiety

### Clinical criteria:

- Patient must be receiving palliative care.

### diazepam 2 mg tablet, 50

5355W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	12.41	13.62	<sup>a</sup> APO-Diazepam [TX]	<sup>a</sup> Valpam 2 [RW]
			<sup>b</sup> 2.99	15.40	13.62	<sup>a</sup> Antenex 2 [AF]	

### diazepam 5 mg tablet, 50

5356X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	12.48	13.69	<sup>a</sup> Antenex 5 [AF]	<sup>a</sup> APO-Diazepam [TX]
			<sup>b</sup> 2.19	14.67	13.69	<sup>a</sup> Ranzepam [RA]	<sup>a</sup> Valpam 5 [RW]
						<sup>a</sup> Valium [RO]	

## OXAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Anxiety

### Clinical criteria:

- Patient must be receiving palliative care.

### oxazepam 15 mg tablet, 25

5371Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*13.93	15.14	<sup>a</sup> Alepam 15 [AF]
			<sup>b</sup> 5.32	*19.25	15.14	<sup>a</sup> Serepax [QA]

### oxazepam 30 mg tablet, 25

5372R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*13.25	14.46	<sup>a</sup> Alepam 30 [AF]	<sup>a</sup> APO-Oxazepam [TX]
			<sup>b</sup> 4.66	*17.91	14.46	<sup>a</sup> Murelax [RW]	
						<sup>a</sup> Serepax [QA]	

## HYPNOTICS AND SEDATIVES

### Benzodiazepine derivatives

# NERVOUS SYSTEM

## ■ NITRAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving palliative care.

### nitrazepam 5 mg tablet, 25

5359C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*14.31	15.52	<sup>a</sup> Alodorm [AF]
			<sup>B</sup> 2.48	*16.79	15.52	<sup>a</sup> Mogadon [IA]

## ■ TEMAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving palliative care.

### temazepam 10 mg tablet, 25

5375X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*13.25	14.46	<sup>a</sup> APO-Temazepam [TX]	<sup>a</sup> Temaze [AF]
						<sup>a</sup> Temtabs [FM]	
			<sup>B</sup> 6.96	*20.21	14.46	<sup>a</sup> Normison [QA]	

# Highly Specialised Drugs Program (Private Hospital)

BLOOD AND BLOOD FORMING ORGANS .....	771
ANTIHEMORRHAGICS.....	771
VITAMIN K AND OTHER HEMOSTATICS .....	771
ANTIANEMIC PREPARATIONS .....	776
OTHER ANTIANEMIC PREPARATIONS .....	776
CARDIOVASCULAR SYSTEM.....	780
ANTIHYPERTENSIVES .....	780
OTHER ANTIHYPERTENSIVES .....	780
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	831
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES .....	831
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES .....	831
HYPOTHALAMIC HORMONES.....	833
ANTIINFECTIVES FOR SYSTEMIC USE .....	837
ANTIBACTERIALS FOR SYSTEMIC USE.....	837
MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS.....	837
ANTIMYCOBACTERIALS .....	838
DRUGS FOR TREATMENT OF TUBERCULOSIS.....	838
ANTIVIRALS FOR SYSTEMIC USE .....	838
DIRECT ACTING ANTIVIRALS .....	838
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	843
ANTINEOPLASTIC AGENTS .....	843
ANTIMETABOLITES.....	843
CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES .....	845
OTHER ANTINEOPLASTIC AGENTS.....	846
IMMUNOSTIMULANTS .....	847
IMMUNOSTIMULANTS .....	847
IMMUNOSUPPRESSANTS.....	857
IMMUNOSUPPRESSANTS .....	857
MUSCULO-SKELETAL SYSTEM.....	974
MUSCLE RELAXANTS .....	974
MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS .....	974
DRUGS FOR TREATMENT OF BONE DISEASES .....	976

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION.....	976
<hr/>	
NERVOUS SYSTEM.....	977
ANTI-PARKINSON DRUGS .....	977
DOPAMINERGIC AGENTS .....	977
PSYCHOLEPTICS.....	977
ANTIPSYCHOTICS.....	977
<hr/>	
RESPIRATORY SYSTEM.....	978
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES .....	978
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES .....	978
COUGH AND COLD PREPARATIONS.....	995
EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS .....	995
OTHER RESPIRATORY SYSTEM PRODUCTS .....	996
OTHER RESPIRATORY SYSTEM PRODUCTS .....	996
<hr/>	
VARIOUS .....	1000
ALL OTHER THERAPEUTIC PRODUCTS .....	1000
ALL OTHER THERAPEUTIC PRODUCTS.....	1000

## ■ BLOOD AND BLOOD FORMING ORGANS

### ■ ANTIHEMORRHAGICS

#### VITAMIN K AND OTHER HEMOSTATICS

##### *Other systemic hemostatics*

### ■ ELTROMBOPAG

**Note** No applications for increased repeats will be authorised.

#### **Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

#### **Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

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### **Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;  
 OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and
- (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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### **Authority required**

Severe thrombocytopenia

Treatment Phase: Second or subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a continuing response to treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**eltrombopag 25 mg tablet, 28**

5827Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1483.55	Revolade [NV]

**eltrombopag 50 mg tablet, 28**

5828R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2919.95	Revolade [NV]

**ROMIPILOSTIM**

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,

- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;  
OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a continuing response to treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No applications for increased repeats will be authorised.

**romiplostim 500 microgram injection, 1 vial**

9699L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1904.40	Nplate [AN]

**romiplostim 250 microgram injection, 1 vial**

9697J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	972.93	Nplate [AN]

■ **ANTIANEMIC PREPARATIONS**

**OTHER ANTIANEMIC PREPARATIONS**

*Other antianemic preparations*

▪ **DARBEPOETIN ALFA**

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**

6492Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*2536.59	Aranesp SureClick [AN]

**darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL syringe**

6490N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1582.99	Aranesp SureClick [AN]

**darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

6365B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3756.43	Aranesp [AN]

**darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL syringe**

6493R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*3756.43	Aranesp SureClick [AN]

**darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6326Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2536.63	Aranesp [AN]

**darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

6322R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*913.59	Aranesp [AN]

**darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6324W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1355.09	Aranesp [AN]

**darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

6323T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1105.07	Aranesp [AN]

**darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

6325X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1582.97	Aranesp [AN]

**darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL syringe**

6488L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*669.79	Aranesp SureClick [AN]

**darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL syringe**

6491P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*2068.75	Aranesp SureClick [AN]

**darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

6320P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*358.97	Aranesp [AN]

**darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

6438W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2068.75	Aranesp [AN]

**darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6321Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*669.71	Aranesp [AN]

## BLOOD AND BLOOD FORMING ORGANS

### darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL syringe

6489M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1105.07	Aranesp SureClick [AN]

### ▪ EPOETIN ALFA

#### Authority required

Anaemia associated with intrinsic renal disease

#### Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

### epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

6205N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*666.05	Eprex 3000 [JC]

### epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

6303R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1239.53	Eprex 6000 [JC]

### epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

6204M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*517.75	Eprex 2000 [JC]

### epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

6251B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*283.11	Eprex 1000 [JC]

### epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

6206P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*846.27	Eprex 4000 [JC]

### epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

6207Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1918.93	Eprex 10000 [JC]

### epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

6434P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3729.35	Eprex 20,000 [JC]

### epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

6302Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1051.63	Eprex 5000 [JC]

### epoetin alfa 40 000 units/mL injection, 1 mL syringe

6339P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1238.45	Eprex 40,000 [JC]

### epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

6305W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1593.67	Eprex 8000 [JC]

### ▪ EPOETIN BETA

#### Authority required

Anaemia associated with intrinsic renal disease

#### Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

### epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes

6485H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1918.93	NeoRecormon [RO]

**epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

6481D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*666.05	NeoRecormon [RO]

**epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes**

6484G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1239.53	NeoRecormon [RO]

**epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes**

6483F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1051.65	NeoRecormon [RO]

**epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes**

6480C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*517.75	NeoRecormon [RO]

**epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes**

6482E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*846.27	NeoRecormon [RO]

**▪ EPOETIN LAMBDA****Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

9593X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1512.27	Novicrit [SZ]

**epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes**

9686T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*490.87	Novicrit [SZ]

**epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

9685R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*268.59	Novicrit [SZ]

**epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

9588P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*996.83	Novicrit [SZ]

**epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

9590R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1176.77	Novicrit [SZ]

**epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes**

9595B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1820.43	Novicrit [SZ]

**epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

9688X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*802.11	Novicrit [SZ]

**epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

9687W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*631.37	Novicrit [SZ]

**▪ METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA****Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

## CARDIOVASCULAR SYSTEM

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

### methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe

9580F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3207.35	Mircera [RO]

### methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9576B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*892.41	Mircera [RO]

### methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9575Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*615.07	Mircera [RO]

### methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9574X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*371.89	Mircera [RO]

### methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9577C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1148.03	Mircera [RO]

### methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9578D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1321.71	Mircera [RO]

### methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9579E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1875.23	Mircera [RO]

## ■ CARDIOVASCULAR SYSTEM

## ■ ANTIHYPERTENSIVES

### OTHER ANTIHYPERTENSIVES

*Antihypertensives for pulmonary arterial hypertension*

## ■ AMBRISENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

#### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- RHC composite assessment; and
  - ECHO composite assessment; and
  - 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

**AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**ambrisentan 10 mg tablet, 30**

9649W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2779.80	Volibris [GK]

**ambrisentan 5 mg tablet, 30**

9648T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2779.80	Volibris [GK]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two

weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not recommence PBS-subsidised treatment with the drug they are ceasing.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition, OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**bosentan 125 mg tablet, 60**

6430K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2342.58	<sup>a</sup> Bosentan APOTEX [TX] <sup>a</sup> Bosentan GH [GQ] <sup>a</sup> Bosentan RBX [RA] <sup>a</sup> BOSLEER [RW]	<sup>a</sup> BOSENTAN-DRLA [RZ] <sup>a</sup> Bosentan Mylan [AF] <sup>a</sup> Bosentan Sandoz [SZ] <sup>a</sup> Tracleer [AT]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

#### **Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

**Clinical criteria:**

- Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND**
- Patient must have not responded to prior PBS-subsidised therapy with this agent, **AND**
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**bosentan 62.5 mg tablet, 60**

6429J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2342.58	<sup>a</sup> Bosentan APOTEX [TX] <sup>a</sup> Bosentan Mylan [AF] <sup>a</sup> Bosentan Sandoz [SZ] <sup>a</sup> Tracleer [AT]	<sup>a</sup> BOSENTAN-DRLA [RZ] <sup>a</sup> Bosentan RBX [RA] <sup>a</sup> BOSLEER [RW]

▪ **EPOPROSTENOL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

## CARDIOVASCULAR SYSTEM

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

### epoprostenol 1.5 mg injection [1 vial] (& inert substance diluent [2 x 50 mL vials], 1 pack

11082G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	77.70	Flolan [GK]

### epoprostenol 1.5 mg injection, 1 vial

10129D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	77.70	Veletri [AT]

### epoprostenol 500 microgram injection, 1 vial

10111E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	43.76	Veletri [AT]

### epoprostenol 500 microgram injection [1 vial] (& inert substance diluent [2 x 50 mL vials], 1 pack

11069N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	43.76	Flolan [GK]

## ■ ILOPROST

### Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with this agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

#### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class IV drug-induced PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

6456T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	432.39	Ventavis [BN]

▪ **MACITENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to

connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats will be authorised.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

### **Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

### **Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**macitentan 10 mg tablet, 30**

10134J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2923.62	Opsumit [AT]

■ **RIOCIGUAT**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) completed authority prescription forms sufficient for dose titration; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available:(i) RHC composite assessment; and(ii) ECHO composite assessment; and(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Grandfathered patients

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised agent for this condition.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) A completed authority prescription form; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(2) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**riociguat 500 microgram tablet, 84**

11008J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 1.5 mg tablet, 84**

10975P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 2 mg tablet, 84**

11017W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 1 mg tablet, 84**

11010L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 1 mg tablet, 42**

10990K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

**riociguat 500 microgram tablet, 42**

11009K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

**riociguat 2.5 mg tablet, 42**

10985E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

**riociguat 2.5 mg tablet, 84**

11018X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 2 mg tablet, 42**

11012N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

**riociguat 1.5 mg tablet, 42**

10974N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

▪ **RIOCIGUAT**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**

- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made two weeks prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 4 (Grandfathered patients)

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a documented history of a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have a documented history of failure to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the

following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** No applications for increased repeats will be authorised.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 5 (Grandfathered patients)

#### **Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have a documented history of WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have a documented history of WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** No applications for increased repeats will be authorised.

**riociguat 500 microgram tablet, 84**

11058B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 1.5 mg tablet, 84**

11061E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 2 mg tablet, 84**

11030M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 1 mg tablet, 84**

11060D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 1 mg tablet, 42**

11028K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

**riociguat 500 microgram tablet, 42**

11031N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

**riociguat 2.5 mg tablet, 42**

11052Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

**riociguat 2.5 mg tablet, 84**

11035T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3482.57	Adempas [BN]

**riociguat 2 mg tablet, 42**

11045H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

**riociguat 1.5 mg tablet, 42**

11046J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1764.86	Adempas [BN]

▪ **SILDENAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

#### **Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition;  
OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Written applications for authorisation under this criterion should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**sildenafil 20 mg tablet, 90**

9605M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	339.66	<sup>a</sup> APO-Sildenafil PHT [TX] <sup>a</sup> Sildenafil AN PHT 20 [EA] <sup>a</sup> Sildenafil Sandoz PHT 20 [SZ]	<sup>a</sup> Revatio [PF] <sup>a</sup> SILDENAFIL-DRx [RZ]

■ **TADALAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

#### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

### **Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not recommence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;

- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**tadalafil 20 mg tablet, 56**

1304P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	835.61	Adcirca [LY]

■ **SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

■ **PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES**

**ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES**

*Other anterior pituitary lobe hormones and analogues*

■ **PEGVISOMANT**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 2.5 mcg/L; and
- 2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**pegvisomant 20 mg injection [1 vial] (& inert substance diluent [1 syringe], 1 pack**

11166Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*586.59	Somavert [PF]

■ **PEGVISOMANT**

**Note** No increase in the maximum number of repeats may be authorised.

HSD (Private)

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 2.5 mcg/L; and
- 2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition., **AND**
  - The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
  - The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.
- Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Acromegaly

Treatment Phase: Grandfathering

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- Patient must have had a documented age- and sex- adjusted insulin- like factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN) prior to commencing non- PBS- subsidised treatment with this drug.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1). Treatment must be ceased if IGF-1 level is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acromegaly Pegvisomant Grandfather PBS Authority Application - Supporting Information Form; and
3. in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
4. a recent result of the IGF-1 level and the date of assessment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

11172B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4225.72	Somavert [PF]

**pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

11167R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4225.72	Somavert [PF]

**pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

11174D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4225.72	Somavert [PF]

**HYPOTHALAMIC HORMONES**

*Somatostatin and analogues*

▪ **LANREOTIDE**

Authority required

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## lanreotide 30 mg modified release injection [1 vial] (& inert substance diluent [2 mL ampoule], 1 pack

6332G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1472.15	Somatuline LA [IS]

### LANREOTIDE

#### Authority required

Acromegaly

#### **Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

#### Authority required

Functional carcinoid tumour

#### **Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

## lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

6425E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4303.15	Somatuline Autogel [IS]

## lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

6424D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3448.15	Somatuline Autogel [IS]

## lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

6423C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2602.65	Somatuline Autogel [IS]

### OCTREOTIDE

#### Authority required

Acromegaly

#### **Clinical criteria:**

- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

#### Authority required

Functional carcinoid tumour

#### **Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

#### Authority required

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 20 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10549F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3526.77	Sandostatin LAR [NV]

**octreotide 10 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10566D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2660.87	Sandostatin LAR [NV]

**octreotide 30 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10558Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4402.07	Sandostatin LAR [NV]

■ **OCTREOTIDE**

**Authority required**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 50 microgram/mL injection, 5 x 1 mL ampoules**

6227R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*651.01	<sup>a</sup> Hospira Pty Limited [PF] <sup>a</sup> Octreotide (SUN) [RA]	<sup>a</sup> Octreotide MaxRx [GQ] <sup>a</sup> Sandostatin 0.05 [NV]

**octreotide 500 microgram/mL injection, 5 x 1 mL ampoules**

6229W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*6241.63	<sup>a</sup> Hospira Pty Limited [PF] <sup>a</sup> Octreotide (SUN) [RA]	<sup>a</sup> Octreotide MaxRx [GQ] <sup>a</sup> Sandostatin 0.5 [NV]

**octreotide 100 microgram/mL injection, 5 x 1 mL ampoules**

6228T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*1283.53	<sup>a</sup> Hospira Pty Limited [PF] <sup>a</sup> Octreotide (SUN) [RA]	<sup>a</sup> Octreotide MaxRx [GQ] <sup>a</sup> Sandostatin 0.1 [NV]

■ **PASIREOTIDE**

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 2.5 micrograms per litre, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) level greater than 1.3 times the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control is defined as:

- 1) Growth hormone level is greater than 2.5 mcg/L; and
- 2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) a signed patient acknowledgment; and
- d) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- e) a recent copy of GH and IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016.

**Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) a signed patient acknowledgment; and
- d) in a patient who has previously been treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Acromegaly

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

#### **Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **pasireotide 60 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10887B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.15	Signifor LAR [NV]

#### **pasireotide 40 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10884W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.15	Signifor LAR [NV]

#### **pasireotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10880P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.15	Signifor LAR [NV]

## ■ ANTIINFECTIVES FOR SYSTEMIC USE

## ■ ANTIBACTERIALS FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

#### *Macrolides*

## ■ AZITHROMYCIN

#### **Authority required**

Mycobacterium avium complex infection

#### **Clinical criteria:**

- The treatment must be for prophylaxis, **AND**

## ANTIINFECTIVES FOR SYSTEMIC USE

- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

### azithromycin 600 mg tablet, 8

6221K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*122.35	Zithromax [PF]

### ■ CLARITHROMYCIN

#### Authority required

Mycobacterium avium complex infection

### clarithromycin 500 mg tablet, 100

6152T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	41.61	APO-Clarithromycin [TX]

## ■ ANTIMYCOBACTERIALS

### DRUGS FOR TREATMENT OF TUBERCULOSIS

*Antibiotics*

### ■ RIFABUTIN

#### Authority required

Mycobacterium avium complex infection

#### Clinical criteria:

- Patient must be human immunodeficiency virus (HIV) positive.

#### Authority required

Mycobacterium avium complex infection

#### Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

### rifabutin 150 mg capsule, 30

6195C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*646.75	Mycobutin [PF]

## ■ ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

### ■ GANCICLOVIR

#### Authority required

Cytomegalovirus disease

Treatment Phase: Prophylaxis

#### Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

#### Authority required

Cytomegalovirus disease

Treatment Phase: Prophylaxis

#### Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

### ganciclovir 500 mg injection, 5 vials

6136Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	1	..	*560.43	Cymevene [RO]

### ■ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Chronic hepatitis C infection

#### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**

- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10623D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	152.75	Ibavyr [IX]

**ribavirin 200 mg tablet, 28**

10923X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	81.15	Ibavyr [IX]

**ribavirin 600 mg tablet, 28**

10675W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	225.55	Ibavyr [IX]

**■ RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10635R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	152.75	Ibavyr [IX]

**ribavirin 200 mg tablet, 28**

10938Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	81.15	Ibavyr [IX]

**ribavirin 600 mg tablet, 28**

10637W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	225.55	Ibavyr [IX]

**■ VALACICLOVIR**
**Authority required**

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

**valaciclovir 500 mg tablet, 100**

6280M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*237.00	<sup>a</sup> APO-Valaciclovir [TX]	<sup>a</sup> Valaciclovir RBX [RA]
			<sup>B</sup> 2.30	*239.30	<sup>a</sup> Valtrex [RW]	

**■ VALGANCICLOVIR**
**Authority required**

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

## ANTIINFECTIVES FOR SYSTEMIC USE

### valganciclovir 50 mg/mL powder for oral liquid, 100 mL

9675F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	11	5	..	*#4396.02	Valcyte [RO]

### valganciclovir 450 mg tablet, 60

6357N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*3631.45	<sup>a</sup> Valcyte [RO]	<sup>a</sup> Valganciclovir AN [EA]
					<sup>a</sup> Valganciclovir Juno [JU]	<sup>a</sup> Valganciclovir Mylan [AF]
					<sup>a</sup> Valganciclovir Sandoz [SZ]	

### Other antivirals

#### ▪ DACLATASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Chronic hepatitis C infection

##### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

### daclatasvir 30 mg tablet, 28

10630L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7713.82	Daklinza [BQ]

### daclatasvir 60 mg tablet, 28

10631M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7713.82	Daklinza [BQ]

#### ▪ DACLATASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Chronic hepatitis C infection

##### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

### daclatasvir 30 mg tablet, 28

10643E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7713.82	Daklinza [BQ]

### daclatasvir 60 mg tablet, 28

10644F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7713.82	Daklinza [BQ]

#### ▪ GRAZOPRE VIR + ELBASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Chronic hepatitis C infection

##### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

10979W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	21047.15	Zepatier [MK]

▪ **GRAZOPREVIR + ELBASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

10991L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	21047.15	Zepatier [MK]

▪ **LEDIPASVIR + SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10653Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	22113.82	Harvoni [GI]

▪ **LEDIPASVIR + SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10672Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	22113.82	Harvoni [GI]

▪ **LEDIPASVIR + SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

HSD (Private)

## ANTIINFECTIVES FOR SYSTEMIC USE

### ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10679C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22113.82	Harvoni [GI]

#### ■ PARITAPREVR + RITONAVIR + OMBITASVIR & DASABUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Chronic hepatitis C infection

##### **Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

### paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28

10749R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	13900.28	Viekira Pak [VE]

#### ■ PARITAPREVR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Chronic hepatitis C infection

##### **Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

##### **Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

### paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

10750T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	13900.28	Viekira Pak-RBV [VE]

### paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

10753Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	13900.28	Viekira Pak-RBV [VE]

#### ■ PARITAPREVR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Chronic hepatitis C infection

##### **Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

##### **Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack**

10773B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	13900.28	Viekira Pak-RBV [VE]

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack**

10761J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	13900.28	Viekira Pak-RBV [VE]

**▪ SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

10654R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	19344.90	Sovaldi [GI]

**▪ SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

10767X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19344.90	Sovaldi [GI]

**▪ SOFOSBUVIR + VELPATASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

11144M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	22113.82	Epclusa [GI]

**▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS****▪ ANTINEOPLASTIC AGENTS****ANTIMETABOLITES***Pyrimidine analogues*

## ■ AZACITIDINE

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

- 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
- 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
- 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
- Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- a copy of the full blood examination report; and
- a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

### **Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and
- a copy of the full blood examination report; and
- a signed patient acknowledgement.

No more than 3 cycles will be authorised.

### **Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The first authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Azacitidine PBS Authority Application - Supporting Information Form; and

- (c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
  - (d) a copy of the full blood examination report; and
  - (e) a signed patient acknowledgement.
- No more than 3 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

6100C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*5219.35	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> Azadine [RZ] <sup>a</sup> Vidaza [CJ]	<sup>a</sup> AZACITIDINE DR.REDDY'S [RI] <sup>a</sup> Celazadine [JU]

▪ **AZACITIDINE**

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

6138C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*5219.35	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> Azadine [RZ] <sup>a</sup> Vidaza [CJ]	<sup>a</sup> AZACITIDINE DR.REDDY'S [RI] <sup>a</sup> Celazadine [JU]

HSD (Private)

**CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES**

*Anthracyclines and related substances*

▪ **DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL**

**Authority required**

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

**Authority required**

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial

6249X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*1106.35	<sup>a</sup> Caelyx [JC]	<sup>a</sup> Liposomal Doxorubicin SUN [RA]

## OTHER ANTINEOPLASTIC AGENTS

### Monoclonal antibodies

#### ▪ RITUXIMAB

**Note** Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

**Note** Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

#### **Authority required**

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Induction of remission

#### **Clinical criteria:**

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; OR
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

#### **Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Induction of remission

#### **Clinical criteria:**

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; OR
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**Authority required**

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

**Clinical criteria:**

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

**Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

**Clinical criteria:**

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**rituximab 100 mg/10 mL injection, 2 x 10 mL vials**

10583B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	782.68	Mabthera [RO]

**rituximab 500 mg/50 mL injection, 50 mL vial**

10576P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1911.37	Mabthera [RO]

■ **IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**

*Colony stimulating factors*

■ **FILGRASTIM**

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**

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- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes**

5830W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*387.51	Nivestim [PF]

**filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2747N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*958.07	Zarzio [SZ]

**filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2733W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*1512.91	Zarzio [SZ]

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## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### filgrastim 300 microgram/mL injection, 10 x 1 mL vials

6126K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*958.09	Neupogen [AN]

### filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

6127L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1512.93	Neupogen [AN]

### filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes

1113N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1512.93	TevaGrastim [TB]

### filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6292E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1512.93	Neupogen [AN]

### filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9695G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1512.93	Nivestim [PF]

### filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

1082Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*958.09	TevaGrastim [TB]

### filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6291D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*958.09	Neupogen [AN]

### filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9693E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*958.09	Nivestim [PF]

## ■ LENOGRASTIM

### Authority required

Chemotherapy-induced neutropenia

### **Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

### Authority required

Chemotherapy-induced neutropenia

### **Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

### Authority required

Chemotherapy-induced neutropenia

### **Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

### Authority required

Chemotherapy-induced neutropenia

### **Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

### Authority required

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required**

Assisting peripheral blood progenitor cell or bone marrow transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10**

6337M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1019.87	Granocyte 13 [PF]

**LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10**

6338N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*2485.99	Granocyte 34 [PF]

▪ **LIPEGFILGRASTIM**

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

10931H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1297.15	Lonquex [TB]

▪ **PEGFILGRASTIM**

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR

HSD (Private)

- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

6363X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	1297.15	<sup>a</sup> Neulasta [AN]	<sup>a</sup> Ristempa [GV]

*Interferons*

▪ **INTERFERON ALFA-2A**

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**

- The condition must be Philadelphia chromosome positive.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

6210W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*890.35	Roferon-A [RO]

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

6213B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*2594.35	Roferon-A [RO]

**■ INTERFERON ALFA-2B**

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**

- The condition must be Philadelphia chromosome positive.

**Authority required**

Malignant melanoma

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
- Patient must have undergone surgery, **AND**
- The condition must include nodal involvement.

**interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL**

6255F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1179.17	Intron A Redipen [MK]

**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

6254E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*595.81	Intron A Redipen [MK]

**interferon alfa-2b 18 million units/3 mL injection, 3 mL vial**

6218G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	15	5	..	*2594.20	Intron A [MK]

**interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials**

6246R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*1462.18	Intron A [MK]

**interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial**

6219H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	15	5	..	*3584.80	Intron A [MK]

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

6253D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*360.33	Intron A Redipen [MK]

**■ INTERFERON GAMMA-1B**
**Authority required**

Chronic granulomatous disease

**Clinical criteria:**

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

**interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials**

6148N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*2632.87	Imukin [BY]

**■ PEGINTERFERON ALFA-2A**

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- a nurse educator/counsellor for patients; and
- 24-hour access by patients to medical advice; and
- an established liver clinic.

**Authority required**

Chronic hepatitis C infection

**Treatment criteria:**

- Must be treated in an accredited treatment centre.

**Population criteria:**

- Patient must be aged 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

**Clinical criteria:**

- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6449K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2612.59	Pegasys [RO]

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6439X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2262.37	Pegasys [RO]

**PEGINTERFERON ALFA-2A**

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

11044G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	1329.87	Pegasys [RO]

**Other immunostimulants**
**PLERIXAFOR**

**Note** Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

**Authority required**

Mobilisation of haematopoietic stem cells

**Clinical criteria:**

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; OR
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**plerixafor 24 mg/1.2 mL subcutaneous infusion injection, 1.2 mL vial**

10084R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	7038.15	Mozobil [GZ]

## ■ IMMUNOSUPPRESSANTS

### IMMUNOSUPPRESSANTS

#### *Selective immunosuppressants*

## ■ ABATACEPT

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the

C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- a total active joint count of at least 20 active (swollen and tender) joints; or
- at least 4 active joints from the following list of major joints:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

HSD (Private)

**abatacept 250 mg injection, 1 vial**

9621J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	284.14	Orencia [BQ]

▪ **ALEMTUZUMAB**

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

10246G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	..	..	*34229.14	Lemtrada [GZ]

▪ **ALEMTUZUMAB**

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

Authority required

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

10243D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	..	..	*57017.15	Lemtrada [GZ]

**■ ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than  $30 \times 10^9/L$  and a serum creatinine of greater than  $150 \mu\text{mol/L}$ , **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than  $150 \times 10^9/L$ ; and evidence of two of the following:

- presence of schistocytes on blood film;
- low or absent haptoglobin;
- lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; **AND**

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

- a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

- (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
- (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
- (iv) a renal biopsy consistent with aHUS;
- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application; and
- (7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
- (8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1-balance of supply**; and
- (9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
- (10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
- (11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10182X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5984.65	Soliris [XI]

▪ **ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of

haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

**Clinical criteria:**

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for **Initial Treatment**, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10192K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	5984.65	Soliris [XI]

▪ **ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

HSD (Private)

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

### **Clinical criteria:**

- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 56 weeks of treatment under this restriction.

### **Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
- (2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

### **eculizumab 300 mg/30 mL injection, 30 mL vial**

10521R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	5984.65	Soliris [XI]

### ▪ **ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** **WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
- (2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
- This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

**Clinical criteria:**

- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:
  - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
  - b) an eGFR within +/- 25% from baseline; or
  - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease; and
- (11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and
- (12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and

(13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:

- a) Evidence of a mutation known to confer a high risk of aHUS recurrence;
- b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;
- c) Past family history of aHUS recurrence, especially in first-degree relatives;
- d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

#### **Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count  $<150 \times 10^9/L$ );OR(iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

- a) An increase in eGFR of  $> 25\%$  from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
- b) an eGFR within  $\pm 25\%$  from baseline; or
- c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form(s); and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application, and
- (7) An identified genetic mutation, if applicable; and
- (8) A family history of aHUS if applicable; and
- (9) A history of multiple episodes of aHUS following the treatment break, if applicable; and
- (10) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (11) An inclusion of the individual consequences of recurrent disease; and
- (12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
- (14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

**Clinical criteria:**

- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10194M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	5984.65	Soliris [XI]

▪ **EVEROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**everolimus 750 microgram tablet, 60**

6461C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*2786.59	Certican [NV]

**everolimus 1 mg tablet, 60**

9582H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*3699.71	Certican [NV]

**everolimus 500 microgram tablet, 60**

6460B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*956.81	Certican [NV]

**everolimus 250 microgram tablet, 60**

6459Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*481.99	Certican [NV]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 500 mg tablet, 50**

6209T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*281.47	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Ceptolate [AF] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> CellCept [RO] <sup>a</sup> Mycophenolate AN [EA] <sup>a</sup> Pharmacor Mycophenolate 500 [CR]

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

6364Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*#518.46	CellCept [RO]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Note** Management includes initiation, stabilisation and review of therapy as required.

**Authority required**

Prophylaxis of renal allograft rejection

Treatment Phase: Management

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

**Clinical criteria:**

- The condition must be proven by biopsy.

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.  
The name of the consulting nephrologist must be included in the patient medical records.

**mycophenolate 360 mg enteric tablet, 120**

6370G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*363.99	Myfortic [NV]

**mycophenolate 180 mg enteric tablet, 120**

6369F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*185.59	Myfortic [NV]

■ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

**Authority required**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy )

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 250 mg capsule, 100**

6208R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*281.59	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> CellCept [RO] <sup>a</sup> Pharmacor Mycophenolate 250 [CR]

**mycophenolate Capsule 250 mg, 50**

1837Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	12	5	..	*281.59	<sup>a</sup> Ceptolate [AF]

■ **NATALIZUMAB**

**Caution** Progressive multifocal leukoencephalopathy has been reported with this drug.

**Authority required**

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

**Population criteria:**

- Patient must be aged 18 years or older.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**Authority required**

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
  - Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.
- Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**natalizumab 300 mg/15 mL injection, 15 mL vial**

6924M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1536.79	Tysabri [BD]

**■ SIROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**sirolimus 1 mg tablet, 100**

6436R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1421.47	Rapamune [PF]

**sirolimus 2 mg tablet, 100**

6457W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2795.83	Rapamune [PF]

**sirolimus 1 mg/mL oral liquid, 60 mL**

6437T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*931.91	Rapamune [PF]

**sirolimus 500 microgram tablet, 100**

9748C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*721.81	Rapamune [PF]

**■ VEDOLIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

- an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
- an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is

reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

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#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient – Initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for adalimumab, infliximab or vedolizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment (Grandfather patient)

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, **AND**
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic baseline assessment is not available, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be 18 years of age or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and baseline Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the date of commencement of this drug; and
  - (iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** The patient must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**vedolizumab 300 mg injection, 1 vial**

10398G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3152.34	Entyvio [TK]

▪ **VEDOLIZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to

receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Adalimumab only:** Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Ustekinumab only:** Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient – initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR

- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iv) the date of the most recent clinical assessment; and
  - (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

**Note** This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
  - (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - the date of the most recent clinical assessment; and
  - the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

- (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
- (iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

**vedolizumab 300 mg injection, 1 vial**

10415E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3152.34	Entyvio [TK]

*Tumor necrosis factor alpha (TNF-) inhibitors*

▪ **ADALIMUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

HSD (Private)

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24

weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD

without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure

uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9680L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1327.01	Humira [VE]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9679K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1327.01	Humira [VE]

#### **adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

9678J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1327.01	Humira [VE]

### ▪ ETANERCEPT

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to

Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

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**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9615C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	983.97	Enbrel [PF]

### ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9641K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	983.97	Enbrel [PF]

### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

6367D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	495.57	Enbrel [PF]

## ■ INFLIXIMAB

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Acute severe ulcerative colitis

#### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

#### **Clinical criteria:**

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

#### **Population criteria:**

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

### infliximab 100 mg injection, 1 vial

10057H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

## ■ INFLIXIMAB

**Note** Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au).

Written applications for authority to prescribe infliximab should be forwarded to:  
 Medicare Australia  
 Prior Written Approval of Specialised Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

### **Authority required**

#### **Initial 1**

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

The authority application must be made in writing

### **Authority required**

#### **Initial 2**

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for

adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF- $\alpha$  antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF- $\alpha$  antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
  - (ii) details of prior TNF- $\alpha$  antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

The authority application must be made in writing

#### **Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

- (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
- (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) is receiving treatment with infliximab at the time of application; and
- (e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:
  - (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
  - (ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

The authority application must be made in writing

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

The authority application must be made in writing

**infliximab 100 mg injection, 1 vial**

9674E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

## **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

## **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

## **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

## **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)).

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

- a completed authority prescription form; and
- a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:
  - the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
  - details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the 'Balance of Supply' treatment phase PBS restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for a paediatric patient

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 3 doses or 2 repeats.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

9612X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Adalimumab only:** Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Ustekinumab only:** Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same

treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - the date of the most recent clinical assessment; and
  - the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**

- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

**infliximab 100 mg injection, 1 vial**

9613Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

HSD (Private)

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break

in PBS-subsidised TNF- $\alpha$  antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF- $\alpha$  antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF- $\alpha$  antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF- $\alpha$  antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF- $\alpha$  antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised TNF- $\alpha$  antagonist therapy after 1 June 2017. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF- $\alpha$  antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF- $\alpha$  antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF- $\alpha$  antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- $\alpha$  antagonist. For second and subsequent courses of PBS-subsidised TNF- $\alpha$  antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats. (b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF- $\alpha$  antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF- $\alpha$  antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF- $\alpha$  antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- $\alpha$  antagonist. (2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF- $\alpha$  antagonist is approved, a patient may swap if eligible to the alternate TNF- $\alpha$  antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate agent at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF- $\alpha$  antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF- $\alpha$  antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF- $\alpha$  antagonist the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF- $\alpha$  antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF- $\alpha$  antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured. (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Re-commencement of treatment after more than 5 years break in therapy - Initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

**Population criteria:**

- Patient must be 6 years of age or older.

Applications for authorisation of initial treatment must be in writing and must include:

- a completed authority prescription form; and
- a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
  - details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - the signed patient acknowledgement or guardian acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

The authority application must be made in writing

Up to a maximum of 2 repeats will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of initial treatment must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy];

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction).

**Population criteria:**

- Patient must be 6 years of age or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**infliximab 100 mg injection, 1 vial**

10184B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1);

or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF- $\alpha$  antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment

restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

## **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

## **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with infliximab, **AND**
- Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

6397Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term

treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for commencement after 5 years or more and initial 2 for commencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

#### **Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

#### **Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

**AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

#### **Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

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#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

6448J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of

HSD (Private)

treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and  
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or  
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and  
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**

- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

6496X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

■ **INFLIXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
- (iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

HSD (Private)

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to

determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

### **Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment

Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

9617E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.87	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

HSD (Private)

*Interleukin inhibitors*

▪ **ANAKINRA**

**Note** This drug is not PBS-subsidised for conditions other than CAPS.

**Authority required (STREAMLINED)**

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

**Treatment criteria:**

- Must be treated by a rheumatologist or in consultation with a rheumatologist; OR
  - Must be treated by a clinical immunologist or in consultation with a clinical immunologist.
- A diagnosis of CAPS must be documented in the patient's medical records.

**anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes**

10263E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1697.15	Kineret [FK]

▪ **TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than

12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**

- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

10068X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	114.00	Actemra [RO]

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

10079L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	272.00	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

10060L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	534.16	Actemra [RO]

■ **TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks

of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4

weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**tocilizumab 80 mg/4 mL injection, 4 mL vial**

10073E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	114.00	Actemra [RO]

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

10071C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	272.00	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

10078K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	534.16	Actemra [RO]

▪ **TOCILIZUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing

they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate,

hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- a total active joint count of at least 20 active (swollen and tender) joints; or
- at least 4 active joints from the following list of major joints:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

9671B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	114.00	Actemra [RO]

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

9672C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	272.00	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

9673D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	534.16	Actemra [RO]

▪ **TOCILIZUMAB**

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or
- (iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services

no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.

(4) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

#### **Clinical criteria:**

- Patient must have been diagnosed with systemic juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR
- Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
  - (ii) details of prior treatment including dose and duration of treatment;
  - (iii) pathology reports detailing CRP and platelet count where appropriate; and
- (3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

**Note** Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

#### **Clinical criteria:**

- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, **AND**
- Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retreat tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retreat or commencement of treatment after a break of less than 12 months) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Initial 2 (retreat or commencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

- (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
- (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
- (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

1419Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	114.00	Actemra [RO]

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

1423X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	272.00	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

1464C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	534.16	Actemra [RO]

**■ USTEKINUMAB**

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second

prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**ustekinumab 130 mg/26 mL injection, 26 mL vial**

11164N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*16976.39	Stelara [JC]

*Calcineurin inhibitors*

▪ **CYCLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of transplant rejection

**Clinical criteria:**

- The treatment must be used by organ or tissue transplant recipients.

**cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules**

6109M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	65.25	Sandimmun [NV]

▪ **CYCLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologists.

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

**Authority required**

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Authority required**

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

**Treatment criteria:**

- Must be treated by a nephrologist.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

**cyclosporin 100 mg/mL oral liquid, 50 mL**

6125J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1310.31	Neoral [NV]

**cyclosporin 25 mg capsule, 30**

6352H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*141.19	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 25 [NV]

**cyclosporin 10 mg capsule, 60**

6232B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*85.55	Neoral 10 [NV]

**cyclosporin 50 mg capsule, 30**

6353J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*286.03	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 50 [NV]

**cyclosporin 100 mg capsule, 30**

6354K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*575.39	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 100 [NV]

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ■ TACROLIMUS

**Caution** Careful monitoring of patients is mandatory.

### Authority required

Management of rejection in patients following organ or tissue transplantation

### **Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

### **tacrolimus 1 mg modified release capsule, 60**

9682N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*280.97	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

### **tacrolimus 2 mg capsule, 100**

10879N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1047.15	Tacrolimus Sandoz [SZ]	

### **tacrolimus 5 mg modified release capsule, 30**

9683P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*787.61	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

### **tacrolimus 500 microgram modified release capsule, 30**

9681M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*86.19	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

### **tacrolimus 500 microgram capsule, 100**

6328C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*235.33	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 0.5 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

### **tacrolimus 5 mg capsule, 50**

6217F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1143.59	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 5 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

### **tacrolimus 750 microgram capsule, 100**

10875J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*397.15	Tacrolimus Sandoz [SZ]	

### **tacrolimus 1 mg capsule, 100**

6216E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*463.51	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 1 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

### *Other immunosuppressants*

## ■ LENALIDOMIDE

**Note** Special Pricing Arrangements apply.

### Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR

- 5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
- 6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
- 7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
  - (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.
- Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
  - (b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
  - (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
  - (d) a copy of the full blood examination report; and
  - (e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
  - (f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
  - (g) a signed patient acknowledgement form.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

- (i) a haemoglobin level taken within the last 4 weeks; and
- (ii) the date of the last transfusion; and
- (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and
- (iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**lenalidomide 5 mg capsule, 21**

2798G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5169.91	Revlimid [CJ]

**lenalidomide 10 mg capsule, 21**

2796E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5408.31	Revlimid [CJ]

▪ **LENALIDOMIDE**

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

- (1) less than a 25% reduction in serum or urine M protein; or
- (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
- (3) duration of thalidomide and daily dose prescribed; and
- (4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
 Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Multiple myeloma  
 Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**

- Patient must have previously received an authority prescription for lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**lenalidomide 15 mg capsule, 21**

9644N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6299.68	Revlimid [CJ]

**lenalidomide 5 mg capsule, 21**

9642L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5169.91	Revlimid [CJ]

**lenalidomide 25 mg capsule, 21**

9645P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6634.64	Revlimid [CJ]

**lenalidomide 10 mg capsule, 21**

9643M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5408.31	Revlimid [CJ]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma  
 Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

HSD (Private)

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and
- (3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Patient must be registered in the i-access risk management program.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**lenalidomide 15 mg capsule, 21**

11042E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6299.68	Revlimid [CJ]

**lenalidomide 5 mg capsule, 21**

11036W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5169.91	Revlimid [CJ]

**lenalidomide 25 mg capsule, 21**

11055W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6634.64	Revlimid [CJ]

**lenalidomide 10 mg capsule, 21**

11063G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5408.31	Revlimid [CJ]

■ **POMALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and
- (3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib. Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**pomalidomide 4 mg capsule, 21**

10386P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10547.15	Pomalyst [CJ]

**pomalidomide 3 mg capsule, 21**

10417G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10547.15	Pomalyst [CJ]

▪ **RITUXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Abatacept patients:** Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

**Rituximab patients:** A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

**Rituximab patients:** A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

**Abatacept:** Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

**Rituximab:** In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or  
 (b) at least 4 active joints from the following list of major joints:  
 (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
 (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
 The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;  
 (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;  
 (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and  
 (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  
 (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:  
 (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**rituximab 500 mg/50 mL injection, 50 mL vial**

9611W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1911.37	Mabthera [RO]

▪ **THALIDOMIDE**

**Caution** Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

**Authority required**

Multiple myeloma

**thalidomide 100 mg capsule, 28**

9684Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1643.15	Thalomid [CJ]

**thalidomide 50 mg capsule, 28**

6469L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*1643.15	Thalomid [CJ]

▪ **MUSCULO-SKELETAL SYSTEM**

▪ **MUSCLE RELAXANTS**

**MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS**

*Other centrally acting agents*

## ▪ BACLOFEN

### Authority required

Severe chronic spasticity

### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

### Authority required

Severe chronic spasticity

### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

### Authority required

Severe chronic spasticity

### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

### Authority required

Severe chronic spasticity

### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

### baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule

11194E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1043.83	Sintetica Baclofen Intrathecal [BZ]

## ▪ BACLOFEN

**Note** Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

### Authority required

Severe chronic spasticity

### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

### Authority required

Severe chronic spasticity

### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

### Authority required

Severe chronic spasticity

### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

### Authority required

Severe chronic spasticity

### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

### baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule

6284R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*1293.45	<sup>a</sup> Bacthecal [DZ]	<sup>a</sup> Lioresal Intrathecal [NV]

## MUSCULO-SKELETAL SYSTEM

### baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules

11128Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1293.45	<sup>a</sup> Sintetica Baclofen Intrathecal [BZ]

## DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

#### Bisphosphonates

#### IBANDRONATE

##### Authority required

Bone metastases

##### Clinical criteria:

- The condition must be due to breast cancer.

### ibandronate 6 mg/6 mL injection, 6 mL vial

9619G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	344.41	Bondronat [RO]

#### PAMIDRONATE DISODIUM

##### Authority required

Hypercalcaemia of malignancy

##### Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

### pamidronate disodium 60 mg/10 mL injection, 10 mL vial

6288Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	66.41	Pamisol [PF]

### pamidronate disodium 15 mg/5 mL injection, 5 mL vial

6286W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	2	..	*66.39	Pamisol [PF]

### pamidronate disodium 30 mg/10 mL injection, 10 mL vial

6287X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*66.41	Pamisol [PF]

#### PAMIDRONATE DISODIUM

##### Authority required

Hypercalcaemia of malignancy

##### Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

##### Authority required

Multiple myeloma

##### Authority required

Bone metastases

##### Clinical criteria:

- The condition must be due to breast cancer.

### pamidronate disodium 90 mg/10 mL injection, 10 mL vial

6289B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	94.04	Pamisol [PF]

#### ZOLEDRONIC ACID

**Note** Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

##### Authority required

Multiple myeloma

##### Authority required

Bone metastases

##### Clinical criteria:

- The condition must be due to breast cancer.

##### Authority required

Bone metastases

##### Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

**Authority required**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**zoledronic acid 4 mg/100 mL injection, 100 mL bag**

10542W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	262.29	<sup>a</sup> DBL Zoledronic Acid [PF]

**zoledronic acid 4 mg/100 mL injection, 100 mL vial**

10554L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	262.29	<sup>a</sup> Zometa [NV]

**zoledronic acid 4 mg/5 mL injection, 5 mL vial**

6371H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	262.29	<sup>a</sup> APO-Zoledronic Acid [TX] <sup>a</sup> Zometa [NV]	<sup>a</sup> DBL Zoledronic Acid [PF]

## ■ NERVOUS SYSTEM

### ■ ANTI-PARKINSON DRUGS

#### DOPAMINERGIC AGENTS

*Dopa and dopa derivatives*

#### ■ LEVODOPA + CARBIDOPA ANHYDROUS

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required**

Advanced Parkinson disease

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

9744W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11583.15	Duodopa [VE]

*Dopamine agonists*

#### ■ APOMORPHINE

**Authority required**

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules**

9640J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8215.15	Movapo [TD]

**apomorphine hydrochloride 100 mg/20 mL injection, 5 x 20 mL vials**

11083H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	5	..	*7599.91	Apomine Solution for Infusion [PF]

**apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules**

9607P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	72	5	..	*6576.43	Movapo [TD]

**apomorphine hydrochloride 50 mg/10 mL injection, 5 x 10 mL syringes**

10971K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8215.15	Movapo PFS [TD]

## ■ PSYCHOLEPTICS

#### ANTIPSYCHOTICS

*Diazepines, oxazepines, thiazepines and oxepines*

## ■ CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

### Authority required

Schizophrenia

Treatment Phase: Initial treatment

### Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

### Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

### clozapine 200 mg tablet, 100

6418T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*511.31	Clopine 200 [PF]

### clozapine 100 mg tablet, 100

6102E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*259.23	<sup>a</sup> Clopine 100 [PF]	<sup>a</sup> Clozaril 100 [NV]

### clozapine 25 mg tablet, 100

6101D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*75.79	<sup>a</sup> Clopine 25 [PF]	<sup>a</sup> Clozaril 25 [NV]

### clozapine 50 mg tablet, 100

6417R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*141.61	Clopine 50 [PF]

### clozapine 50 mg/mL oral liquid, 100 mL

9632Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	147.55	Clopine Suspension [PF]

## ■ RESPIRATORY SYSTEM

## ■ DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

#### *Other systemic drugs for obstructive airway diseases*

## ■ MEPOLIZUMAB

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA**  
Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length

of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
- iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 6 weeks, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
- (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, **OR** a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, **OR** 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
  - (iii) the signed patient or parent/guardian acknowledgement; and
- (c) a copy of the eosinophil pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**mepolizumab 100 mg injection, 1 vial**

11003D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	1685.15	Nucala [GK]

▪ **MEPOLIZUMAB**

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA**

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
- iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

## (b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

## (c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

## (2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

## (3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to mepolizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with mepolizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 26 to 30 weeks after the first dose of PBS-subsidised mepolizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with mepolizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** It is recommended that second and subsequent applications for continuing treatment are submitted at the time of an 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment - grandfather patients

#### **Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of mepolizumab, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of mepolizumab, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of mepolizumab, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to mepolizumab therapy despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with mepolizumab, **AND**
- The treatment must not be used in combination with omalizumab.

#### **Population criteria:**

- Patient must be aged 12 years or older.

#### **Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
- (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-mepolizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with mepolizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
  - (ii) details of pre- and post-mepolizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and
  - (iii) the signed patient or parent/guardian acknowledgement; and
- (c) a copy of the pre-mepolizumab eosinophil pathology report.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### mepolizumab 100 mg injection, 1 vial

11014Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1685.15	Nucala [GK]

### ■ OMALIZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

#### **Clinical criteria:**

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

- 1) a H2 receptor antagonist (150 mg twice per day); or
- 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
- 3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:
  - (i) demonstration of failure to achieve an adequate response to standard therapy; and
  - (ii) drug names and doses of standard therapies that the patient has failed; and
  - (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**omalizumab 150 mg/mL injection, 1 mL syringe**

11175E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*859.95	Xolair [NV]

▪ **OMALIZUMAB**

**Authority required**

Severe chronic spontaneous urticaria  
Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

**Note** A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note** Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe chronic spontaneous urticaria  
Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- Patient must have documented history of itch and hives that persisted on a daily basis for at least 6 weeks despite treatment with H1 antihistamines prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have documented history of failure to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

- 1) a H2 receptor antagonist (150 mg twice per day); or
- 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
- 3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial Grandfather PBS Authority Application - Supporting Information Form which must include:

- (i) demonstration of failure to achieve an adequate response to standard therapy; and
- (ii) drug names and doses of standard therapies that the patient has failed; and
- (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### omalizumab 150 mg/mL injection, 1 mL syringe

11163M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*859.95	Xolair [NV]

## ■ OMALIZUMAB

**Note** Special Pricing Arrangements apply.

### Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

### Clinical criteria:

- Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

### Population criteria:

- Patient must be aged 6 to less than 12 years.

### Treatment criteria:

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

### Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; **AND**

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), **AND**

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an

interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
  - (iii) acknowledgement signed by a parent or authorised guardian; and
- (c) a copy of the IgE pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the prescriber's signature.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers

may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR
- (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial and continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction or Grandfather treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing or Grandfather restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing or grandfather restrictions may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Grandfather patients

### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of omalizumab, a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of omalizumab, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to omalizumab therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated an adequate response to treatment.

### **Population criteria:**

- Patient must be aged 6 to less than 12 years.

### **Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; **AND**

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

(i) a reduction in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire Interviewer Administered (ACQ-IA) score of at least 0.5;

(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or

(iii) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

Patients will be eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for an initial course of omalizumab of up to 24 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Grandfather Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

- (ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and
- (iii) acknowledgement signed by a parent or authorised guardian.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**omalizumab 150 mg/mL injection, 1 mL syringe**

10968G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	433.55	Xolair [NV]

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

10956P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.35	Xolair [NV]

**■ OMALIZUMAB**

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
- (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, **OR** a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
  - (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, **OR** 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.
- The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline

IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
  - (iii) the signed patient or parent/guardian acknowledgement; and
- (c) the IgE pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
- iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic

reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

#### **Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose, and the assessment of time adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber; for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or

iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### omalizumab 150 mg/mL injection, 1 mL syringe

10122R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	433.55	Xolair [NV]

### omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10110D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.35	Xolair [NV]

## COUGH AND COLD PREPARATIONS

### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

#### *Mucolytics*

#### ▪ DORNASE ALFA

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

#### Authority required

Cystic fibrosis

#### Population criteria:

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

#### Authority required

Cystic fibrosis

#### Clinical criteria:

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

#### Population criteria:

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

#### Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

## RESPIRATORY SYSTEM

### Population criteria:

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

### dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

6120D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2289.15	Pulmozyme [RO]

### ■ MANNITOL

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

#### Authority required

Cystic fibrosis

#### **Clinical criteria:**

- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; **AND**

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

### MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1

2008Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1783.15	bronchitol [XA]

## ■ OTHER RESPIRATORY SYSTEM PRODUCTS

### OTHER RESPIRATORY SYSTEM PRODUCTS

*Other respiratory system products*

### ■ IVACAFTOR

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

#### **Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

#### **Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
- (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
- (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (7) a copy of a sweat chloride result; and
- (8) height and weight measurements at the time of application; and
- (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

#### **Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

#### **Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and

- (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
- (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older.  
Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (5) height and weight measurements at the time of application; and
- (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

**ivacaftor 150 mg tablet, 56**

10175M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22547.15	Kalydeco [VR]

■ **IVACAFTOR**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
- (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
- (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older.  
Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (7) a copy of a sweat chloride result; and
- (8) height and weight measurements at the time of application; and
- (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
- (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (5) height and weight measurements at the time of application; and
- (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have received treatment with ivacaftor for this condition prior to 1 May 2017, **AND**
- Patient must have received treatment with ivacaftor within the last 6 months at the time of application, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 2 to 5 years of age.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
- (3) an acknowledgement signed by a parent, or authorised guardian if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
- (5) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (6) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
- (7) height and weight measurements at the time of application; and
- (8) height and weight measurements performed immediately prior to commencement of ivacaftor; and
- (9) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
- (10) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and
- (11) dates of prior ivacaftor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ivacaftor 75 mg granules, 4 x 14 sachets**

11109Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22547.15	Kalydeco [VR]

**ivacaftor 50 mg granules, 4 x 14 sachets**

11097C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22547.15	Kalydeco [VR]

■ **VARIOUS**  
 ■ **ALL OTHER THERAPEUTIC PRODUCTS**  
**ALL OTHER THERAPEUTIC PRODUCTS**  
*Iron chelating agents*

■ **DEFERASIROX**

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic iron overload

**Clinical criteria:**

- Patient must have a disorder of erythropoiesis.

**deferasirox 500 mg dispersible tablet, 28**

9600G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*5372.71	Exjade [NV]

**deferasirox 125 mg dispersible tablet, 28**

6499C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*1378.57	Exjade [NV]

**deferasirox 250 mg dispersible tablet, 28**

6500D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2709.91	Exjade [NV]

**▪ DEFERIPRONE****Authority required**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

**Authority required**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

**deferiprone 500 mg tablet, 100**

6416Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2615.35	Ferriprox [TX]

**deferiprone 100 mg/mL oral liquid, 250 mL**

9638G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	5	..	*1117.25	Ferriprox [TX]

**▪ DEFERRIOXAMINE****Authority required**

Disorders of erythropoiesis

**Clinical criteria:**

- The condition must be associated with treatment-related chronic iron overload.

**desferrioxamine mesilate 2 g injection, 1 vial**

6270B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	60	5	..	*1915.75	Hospira Pty Limited [PF]

**desferrioxamine mesilate 500 mg injection, 10 vials**

6113R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	40	5	..	*4301.95	Hospira Pty Limited [PF]

***Drugs for treatment of hyperkalemia and hyperphosphatemia*****▪ LANTHANUM****Authority required**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**

9637F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*886.49	Fosrenol [ZI]

**LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**

9635D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*524.41	Fosrenol [ZI]

**LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**

9636E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*788.23	Fosrenol [ZI]

▪ **SEVELAMER**

**Authority required**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer hydrochloride 800 mg tablet, 180**

9620H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*619.71	Renagel [GZ]

▪ **SUCROFERRIC OXYHYDROXIDE**

**Authority required**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90**

10230K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*790.75	Velphoro [FN]

# Highly Specialised Drugs Program (Public Hospital)

BLOOD AND BLOOD FORMING ORGANS .....	1005
ANTIHEMORRHAGICS.....	1005
VITAMIN K AND OTHER HEMOSTATICS .....	1005
ANTIANEMIC PREPARATIONS .....	1010
OTHER ANTIANEMIC PREPARATIONS .....	1010
CARDIOVASCULAR SYSTEM.....	1014
ANTIHYPERTENSIVES .....	1014
OTHER ANTIHYPERTENSIVES .....	1014
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	1065
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES .....	1065
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES .....	1065
HYPOTHALAMIC HORMONES.....	1067
ANTIINFECTIVES FOR SYSTEMIC USE .....	1072
ANTIBACTERIALS FOR SYSTEMIC USE.....	1072
MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS.....	1072
ANTIMYCOBACTERIALS .....	1072
DRUGS FOR TREATMENT OF TUBERCULOSIS.....	1072
ANTIVIRALS FOR SYSTEMIC USE .....	1072
DIRECT ACTING ANTIVIRALS .....	1072
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	1078
ANTINEOPLASTIC AGENTS .....	1078
ANTIMETABOLITES.....	1078
CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES .....	1080
OTHER ANTINEOPLASTIC AGENTS.....	1080
IMMUNOSTIMULANTS .....	1081
IMMUNOSTIMULANTS .....	1081
IMMUNOSUPPRESSANTS.....	1092
IMMUNOSUPPRESSANTS .....	1092
MUSCULO-SKELETAL SYSTEM.....	1210
MUSCLE RELAXANTS .....	1210
MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS .....	1210
DRUGS FOR TREATMENT OF BONE DISEASES .....	1211

---

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION..... 1211

---

NERVOUS SYSTEM..... 1212

ANTI-PARKINSON DRUGS ..... 1212

DOPAMINERGIC AGENTS ..... 1212

PSYCHOLEPTICS..... 1213

ANTIPSYCHOTICS..... 1213

---

RESPIRATORY SYSTEM..... 1214

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES ..... 1214

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY  
DISEASES ..... 1214

COUGH AND COLD PREPARATIONS..... 1230

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH  
SUPPRESSANTS ..... 1230

OTHER RESPIRATORY SYSTEM PRODUCTS ..... 1232

OTHER RESPIRATORY SYSTEM PRODUCTS ..... 1232

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VARIOUS ..... 1236

ALL OTHER THERAPEUTIC PRODUCTS ..... 1236

ALL OTHER THERAPEUTIC PRODUCTS..... 1236

## ■ BLOOD AND BLOOD FORMING ORGANS

### ■ ANTIHEMORRHAGICS

#### VITAMIN K AND OTHER HEMOSTATICS

##### *Other systemic hemostatics*

### ■ ELTROMBOPAG

**Note** No applications for increased repeats will be authorised.

#### **Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

#### **Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

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### **Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;  
 OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and
- (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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### **Authority required**

Severe thrombocytopenia

Treatment Phase: Second or subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a continuing response to treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**eltrombopag 25 mg tablet, 28**

5825N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1436.40	Revolade [NV]

**eltrombopag 50 mg tablet, 28**

5826P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2872.80	Revolade [NV]

**ROMIPILOSTIM**

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,

- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,  
 (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and  
 (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

#### **Population criteria:**

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;  
OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a continuing response to treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No applications for increased repeats will be authorised.

**romiplostim 500 microgram injection, 1 vial**

9698K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1857.25	Nplate [AN]

**romiplostim 250 microgram injection, 1 vial**

9696H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	928.63	Nplate [AN]

■ **ANTIANEMIC PREPARATIONS**

**OTHER ANTIANEMIC PREPARATIONS**

*Other antianemic preparations*

▪ **DARBEPOETIN ALFA****Authority required (STREAMLINED)****6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**

5649H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*2489.44	Aranesp SureClick [AN]

**darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL syringe**

5647F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1535.84	Aranesp SureClick [AN]

**darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

5643B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3709.28	Aranesp [AN]

**darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL syringe**

5650J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*3709.28	Aranesp SureClick [AN]

**darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

5651K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2489.48	Aranesp [AN]

**darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

5639T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*871.58	Aranesp [AN]

**darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

5641X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1307.94	Aranesp [AN]

**darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

5640W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1057.92	Aranesp [AN]

**darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

5642Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1535.82	Aranesp [AN]

**darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL syringe**

5645D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*637.12	Aranesp SureClick [AN]

**darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL syringe**

5648G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*2021.60	Aranesp SureClick [AN]

**darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

5637Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*338.28	Aranesp [AN]

**darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

5644C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2021.60	Aranesp [AN]

**darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

5638R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*637.08	Aranesp [AN]

## BLOOD AND BLOOD FORMING ORGANS

### darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL syringe

5646E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1057.92	Aranesp SureClick [AN]

### ▪ EPOETIN ALFA

#### Authority required (STREAMLINED)

**6294**

Anaemia associated with intrinsic renal disease

#### Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

### epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

5720C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*633.56	Epex 3000 [JC]

### epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

5716W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1192.38	Epex 6000 [JC]

### epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

5719B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*490.96	Epex 2000 [JC]

### epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

5714R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*265.34	Epex 1000 [JC]

### epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

5721D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*806.84	Epex 4000 [JC]

### epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

5722E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1871.78	Epex 10000 [JC]

### epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

5713Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3682.20	Epex 20,000 [JC]

### epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

5715T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1004.48	Epex 5000 [JC]

### epoetin alfa 40 000 units/mL injection, 1 mL syringe

5718Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1191.30	Epex 40,000 [JC]

### epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

5717X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1546.52	Epex 8000 [JC]

### ▪ EPOETIN BETA

#### Authority required (STREAMLINED)

**6294**

Anaemia associated with intrinsic renal disease

#### Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes**

5729M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1871.78	NeoRecormon [RO]

**epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

5725H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*633.56	NeoRecormon [RO]

**epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes**

5728L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1192.38	NeoRecormon [RO]

**epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes**

5727K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1004.50	NeoRecormon [RO]

**epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes**

5724G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*490.96	NeoRecormon [RO]

**epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes**

5726J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*806.84	NeoRecormon [RO]

■ **EPOETIN LAMBDA**

**Authority required (STREAMLINED)**

**6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

9594Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1465.12	Novicrit [SZ]

**epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes**

9669X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*465.12	Novicrit [SZ]

**epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

9668W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*251.38	Novicrit [SZ]

**epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

9589Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*951.62	Novicrit [SZ]

**epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

9591T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1129.62	Novicrit [SZ]

**epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes**

9596C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1773.28	Novicrit [SZ]

**epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

9587N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*764.38	Novicrit [SZ]

**epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

9670Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*600.22	Novicrit [SZ]

▪ METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

**Authority required (STREAMLINED)**

6294

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe**

5800G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3160.20	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

5796C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*851.22	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

5795B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*584.54	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

5794Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*350.72	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

5797D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1100.88	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

5798E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1274.56	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

5799F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1828.08	Mircera [RO]

▪ **CARDIOVASCULAR SYSTEM**

▪ **ANTIHYPERTENSIVES**

**OTHER ANTIHYPERTENSIVES**

*Antihypertensives for pulmonary arterial hypertension*

▪ **AMBRISENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not recommence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

### **Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**ambrisentan 10 mg tablet, 30**

5608E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2732.65	Volibris [GK]

**ambrisentan 5 mg tablet, 30**

5607D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2732.65	Volibris [GK]

■ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

### **Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH

agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**bosentan 125 mg tablet, 60**

5619R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2295.43	<sup>a</sup> Bosentan APOTEX [TX] <sup>a</sup> Bosentan GH [GQ]	<sup>a</sup> BOSENTAN-DRLA [RZ] <sup>a</sup> Bosentan Mylan [AF]

<sup>a</sup> Bosentan RBX [RA]  
<sup>a</sup> BOSLEER [RW]

<sup>a</sup> Bosentan Sandoz [SZ]  
<sup>a</sup> Tracleer [AT]

■ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent;  
OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

**Clinical criteria:**

- Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND**
  - Patient must have not responded to prior PBS-subsidised therapy with this agent, **AND**
  - The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, **AND**
  - The treatment must be the sole PBS-subsidised PAH agent for this condition.
- The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**bosentan 62.5 mg tablet, 60**

5618Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2295.43	<sup>a</sup> Bosentan APOTEX [TX] <sup>a</sup> Bosentan Mylan [AF] <sup>a</sup> Bosentan Sandoz [SZ] <sup>a</sup> Tracleer [AT]	<sup>a</sup> BOSENTAN-DRLA [RZ] <sup>a</sup> Bosentan RBX [RA] <sup>a</sup> BOSLEER [RW]

▪ **EPOPROSTENOL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

#### **Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack**

11065J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	66.55	Flolan [GK]

**epoprostenol 1.5 mg injection, 1 vial**

10117L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	66.55	Veletri [AT]

**epoprostenol 500 microgram injection, 1 vial**

10130E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	33.28	Veletri [AT]

**epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack**

11090Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	33.28	Flolan [GK]

■ **ILOPROST**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with this agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

#### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class IV drug-induced PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and

- (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: First Continuing treatment

### **Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

## **Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Subsequent Continuing treatment

### **Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
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**iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

5751Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	408.88	Ventavis [BN]

▪ **MACITENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats will be authorised.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

### **Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition;  
OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

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**macitentan 10 mg tablet, 30**

10136L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2876.47	Opsumit [AT]

▪ **RIOCIGUAT**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) completed authority prescription forms sufficient for dose titration; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

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HOBART TAS 7001

#### **Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### **Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available:(i) RHC composite assessment; and(ii) ECHO composite assessment; and(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)  
Treatment Phase: Grandfathered patients

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised agent for this condition.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) A completed authority prescription form; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(2) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)  
Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**riociguat 500 microgram tablet, 84**

10995Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 1.5 mg tablet, 84**

10977R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 2 mg tablet, 84**

11013P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 1 mg tablet, 84**

11020B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 1 mg tablet, 42**

10976Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

**riociguat 500 microgram tablet, 42**

11001B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

**riociguat 2.5 mg tablet, 42**

11002C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

**riociguat 2.5 mg tablet, 84**

11019Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 2 mg tablet, 42**

10984D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

**riociguat 1.5 mg tablet, 42**

10989J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

▪ **RIOCIGUAT**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

### **Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made two weeks prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

### **Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 4 (Grandfathered patients)

### **Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a documented history of a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have a documented history of failure to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** No applications for increased repeats will be authorised.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 5 (Grandfathered patients)

#### **Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have a documented history of WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

- Patient must have a documented history of WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Note** No applications for increased repeats will be authorised.

**riociguat 500 microgram tablet, 84**

11059C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 1.5 mg tablet, 84**

11048L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 2 mg tablet, 84**

11039B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 1 mg tablet, 84**

11053R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 1 mg tablet, 42**

11054T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

**riociguat 500 microgram tablet, 42**

11040C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

**riociguat 2.5 mg tablet, 42**

11057Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

**riociguat 2.5 mg tablet, 84**

11024F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

**riociguat 2 mg tablet, 42**

11038Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

**riociguat 1.5 mg tablet, 42**

11047K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

▪ **SILDENAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and

- (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**

- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

#### **Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**sildenafil 20 mg tablet, 90**

9547L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	319.72	<sup>a</sup> APO-Sildenafil PHT [TX] <sup>a</sup> Sildenafil AN PHT 20 [EA] <sup>a</sup> Sildenafil Sandoz PHT 20 [SZ]	<sup>a</sup> Revatio [PF] <sup>a</sup> SILDENAFIL-DRx [RZ]

▪ **TADALAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

#### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

#### **Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

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**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
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Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

#### **Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition;  
OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Written applications for authorisation under this criterion should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

### tadalafil 20 mg tablet, 56

1308W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	796.60	Adcirca [LY]

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

#### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

*Other anterior pituitary lobe hormones and analogues*

#### PEGVISOMANT

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### Authority required

Acromegaly

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 2.5 mcg/L; and
- 2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

No increase in the maximum quantity or number of units may be authorised for the loading dose.

### pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack

11177G	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*557.16	Somavert [PF]

#### ■ PEGVISOMANT

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Acromegaly

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 2.5 mcg/L; and
- 2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Acromegaly

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition., **AND**
  - The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
  - The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.
- Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **Authority required**

Acromegaly

Treatment Phase: Grandfathering

### **Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- Patient must have had a documented age- and sex- adjusted insulin- like factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN) prior to commencing non- PBS- subsidised treatment with this drug.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1). Treatment must be ceased if IGF-1 level is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acromegaly Pegvisomant Grandfather PBS Authority Application - Supporting Information Form; and
3. in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
4. a recent result of the IGF-1 level and the date of assessment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **pegvisomant 15 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11173C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4178.57	Somavert [PF]

### **pegvisomant 10 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11179J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4178.57	Somavert [PF]

### **pegvisomant 20 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11181L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4178.57	Somavert [PF]

## HYPOTHALAMIC HORMONES

### *Somatostatin and analogues*

#### ▪ LANREOTIDE

### **Authority required (STREAMLINED)**

**7042**

Acromegaly

### **Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), **AND**
  - The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
  - The treatment must not be given concomitantly with PBS-subsidised pegvisomant.
- In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

### lanreotide 30 mg modified release injection [1 vial] (& inert substance diluent [2 mL ampoule], 1 pack

5776B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1425.00	Somatuline LA [IS]

#### ■ LANREOTIDE

##### Authority required (STREAMLINED)

##### **7025**

Acromegaly

##### **Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

##### Authority required (STREAMLINED)

##### **4575**

Functional carcinoid tumour

##### **Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

### lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

5779E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4256.00	Somatuline Autogel [IS]

### lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

5778D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3401.00	Somatuline Autogel [IS]

### lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

5777C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2555.50	Somatuline Autogel [IS]

#### ■ OCTREOTIDE

##### Authority required (STREAMLINED)

##### **7029**

Acromegaly

##### **Clinical criteria:**

- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

##### Authority required (STREAMLINED)

**5901**

Functional carcinoid tumour

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**5906**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 20 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10533J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3479.62	Sandostatin LAR [NV]

**octreotide 10 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10543X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2613.72	Sandostatin LAR [NV]

**octreotide 30 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10550G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4354.92	Sandostatin LAR [NV]

▪ **OCTREOTIDE**

**Authority required (STREAMLINED)**

**7028**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

**6390**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**6369**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

### octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

9508K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*619.02	<sup>a</sup> Hospira Pty Limited [PF] <sup>a</sup> Octreotide (SUN) [RA]	<sup>a</sup> Octreotide MaxRx [GQ] <sup>a</sup> Sandostatin 0.05 [NV]

### octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

9510M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*6194.52	<sup>a</sup> Hospira Pty Limited [PF] <sup>a</sup> Octreotide (SUN) [RA]	<sup>a</sup> Octreotide MaxRx [GQ] <sup>a</sup> Sandostatin 0.5 [NV]

### octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

9509L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*1236.42	<sup>a</sup> Hospira Pty Limited [PF] <sup>a</sup> Octreotide (SUN) [RA]	<sup>a</sup> Octreotide MaxRx [GQ] <sup>a</sup> Sandostatin 0.1 [NV]

## ■ PASIREOTIDE

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

### Authority required

Acromegaly

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 2.5 micrograms per litre, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) level greater than 1.3 times the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

### **Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control is defined as:

- 1) Growth hormone level is greater than 2.5 mcg/L; and
- 2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) a signed patient acknowledgment; and
- d) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- e) a recent copy of GH and IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Reply Paid 9826  
HOBART TAS 7001

## Authority required

Acromegaly

Treatment Phase: Grandfathering treatment

### **Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016.

### **Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) a signed patient acknowledgment; and
- d) in a patient who has previously been treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## Authority required

Acromegaly

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

### **Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **pasireotide 60 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10882R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

## **pasireotide 40 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10883T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

## **pasireotide 20 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10886Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

■ ANTIINFECTIVES FOR SYSTEMIC USE

■ ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

*Macrolides*

■ AZITHROMYCIN

Authority required (STREAMLINED)

**6356**

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**azithromycin 600 mg tablet, 8**

5616N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*110.76	Zithromax [PF]

■ CLARITHROMYCIN

Authority required (STREAMLINED)

**5874**

Mycobacterium avium complex infection

**clarithromycin 500 mg tablet, 100**

5624B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	31.33	APO-Clarithromycin [TX]

■ ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

*Antibiotics*

■ RIFABUTIN

Authority required (STREAMLINED)

**6350**

Mycobacterium avium complex infection

**Clinical criteria:**

- Patient must be human immunodeficiency virus (HIV) positive.

Authority required (STREAMLINED)

**6356**

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**rifabutin 150 mg capsule, 30**

9541E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*615.00	Mycobutin [PF]

■ ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

■ GANCICLOVIR

Authority required (STREAMLINED)

**4972**

Cytomegalovirus disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)

**4999**

Cytomegalovirus disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**ganciclovir 500 mg injection, 5 vials**

5749N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	1	..	*532.00	Cymevene [RO]

▪ **RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10646H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	140.00	lbavyr [IX]

**ribavirin 200 mg tablet, 28**

10914K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	70.00	lbavyr [IX]

**ribavirin 600 mg tablet, 28**

10638X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	210.00	lbavyr [IX]

▪ **RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10678B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	140.00	lbavyr [IX]

**ribavirin 200 mg tablet, 28**

10929F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	70.00	lbavyr [IX]

**ribavirin 600 mg tablet, 28**

10663F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	210.00	lbavyr [IX]

▪ **VALACICLOVIR**

**Authority required (STREAMLINED)**

5975

Cytomegalovirus infection and disease

HSD (Public)

## ANTIINFECTIVES FOR SYSTEMIC USE

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

**valaciclovir 500 mg tablet, 100**

9568N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*221.00	<sup>a</sup> APO-Valaciclovir [TX]	<sup>a</sup> Valaciclovir RBX [RA]
			<sup>b</sup> 2.20	*223.20	<sup>a</sup> Valtrex [RW]	

▪ **VALGANCICLOVIR**

**Authority required (STREAMLINED)**

**4989**

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**valganciclovir 50 mg/mL powder for oral liquid, 100 mL**

9655E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	11	5	..	*4346.10	Valcyte [RO]

**valganciclovir 450 mg tablet, 60**

9569P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*3584.30	<sup>a</sup> Valcyte [RO]	<sup>a</sup> Valganciclovir AN [EA]
					<sup>a</sup> Valganciclovir Juno [JU]	<sup>a</sup> Valganciclovir Mylan [AF]
					<sup>a</sup> Valganciclovir Sandoz [SZ]	

*Other antivirals*

▪ **DACLATASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**daclatasvir 30 mg tablet, 28**

10629K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7666.67	Daklinza [BQ]

**daclatasvir 60 mg tablet, 28**

10641C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7666.67	Daklinza [BQ]

▪ **DACLATASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**daclatasvir 30 mg tablet, 28**

10651N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7666.67	Daklinza [BQ]

**daclatasvir 60 mg tablet, 28**

10660C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7666.67	Daklinza [BQ]

**▪ GRAZOPRE VIR + ELBASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

10978T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	21000.00	Zepatier [MK]

**▪ GRAZOPRE VIR + ELBASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

10986F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	21000.00	Zepatier [MK]

**▪ LEDIPASVIR + SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10661D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	22066.67	Harvoni [GI]

**▪ LEDIPASVIR + SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

## ANTIINFECTIVES FOR SYSTEMIC USE

### ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10667K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	22066.67	Harvoni [GI]

#### ▪ LEDIPASVIR + SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic hepatitis C infection

#### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

### ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10669M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22066.67	Harvoni [GI]

#### ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic hepatitis C infection

#### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

### paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28

10751W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	13853.13	Viekira Pak [VE]

#### ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic hepatitis C infection

#### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

#### Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

### paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

10768R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	13853.13	Viekira Pak-RBV [VE]

### paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

10752X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	13853.13	Viekira Pak-RBV [VE]

▪ **PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack**

10754B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	13853.13	Viekira Pak-RBV [VE]

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack**

10765N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	13853.13	Viekira Pak-RBV [VE]

▪ **SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

10625F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	19297.75	Sovaldi [GI]

▪ **SOFOSBUVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

10648K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19297.75	Sovaldi [GI]

▪ **SOFOSBUVIR + VELPATASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

HSD (Public)

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

11145N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	22066.67	Eplusa [GI]

■ **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

■ **ANTINEOPLASTIC AGENTS**

**ANTIMETABOLITES**

*Pyrimidine analogues*

■ **AZACITIDINE**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS). Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:
  - a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
  - b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
  - c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
  - d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
  - e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
  - f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (d) a copy of the full blood examination report; and
- (e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- (f) a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

9597D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*5172.16	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> Azadine [RZ] <sup>a</sup> Vidaza [CJ]	<sup>a</sup> AZACITIDINE DR.REDDY'S [RI] <sup>a</sup> Celazadine [JU]

▪ **AZACITIDINE**

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

9598E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*5172.16	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> Azadine [RZ] <sup>a</sup> Vidaza [CJ]	<sup>a</sup> AZACITIDINE DR.REDDY'S [RI] <sup>a</sup> Celazadine [JU]

HSD (Public)

## CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

*Anthracyclines and related substances*

## ▪ DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

Authority required (STREAMLINED)

6234

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

Authority required (STREAMLINED)

6274

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

**doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial**

5705G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*1059.20	<sup>a</sup> Caelyx [JC]	<sup>a</sup> Liposomal Doxorubicin SUN [RA]

## OTHER ANTINEOPLASTIC AGENTS

*Monoclonal antibodies*

## ▪ RITUXIMAB

**Note** Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

**Note** Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Induction of remission

**Clinical criteria:**

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; OR
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**

- Patient must be at risk of end-organ damage or mortality, **AND**
  - Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
- Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

**Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Induction of remission

**Clinical criteria:**

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; OR
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**Authority required**

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

**Clinical criteria:**

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

**Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

**Clinical criteria:**

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**rituximab 100 mg/10 mL injection, 2 x 10 mL vials**

10591K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	745.70	Mabthera [RO]

**rituximab 500 mg/50 mL injection, 50 mL vial**

10593M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1864.22	Mabthera [RO]

■ **IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**

*Colony stimulating factors*

■ **FILGRASTIM**

**Authority required (STREAMLINED)**

**6544**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required (STREAMLINED)****6522**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)****6545**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)****6532**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)****6515**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)****6492**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)****6507**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)****6533**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required (STREAMLINED)**

**6523**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

**6534**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required (STREAMLINED)**

**6535**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

**6536**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required (STREAMLINED)**

**6493**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required (STREAMLINED)**

**6502**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required (STREAMLINED)**

**6516**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required (STREAMLINED)**

**6653**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**6654**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**6679**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

**6655**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

**6680**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

**6621**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

**6640**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes**

5829T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*365.74	Nivestim [PF]

**filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2758E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*914.36	Zarzio [SZ]

**filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2783L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*1465.76	Zarzio [SZ]

**filgrastim 300 microgram/mL injection, 10 x 1 mL vials**

5741E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*914.36	Neupogen [AN]

**filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials**

5743G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1465.78	Neupogen [AN]

**filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes**

1126G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1465.78	TevaGrastim [TB]

**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

5744H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1465.78	Neupogen [AN]

**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

9694F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1465.78	Nivestim [PF]

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

1123D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*914.36	TevaGrastim [TB]

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

5742F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*914.36	Neupogen [AN]

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

9692D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*914.36	Nivestim [PF]

▪ **LENOGRASTIM**

**Authority required (STREAMLINED)**

**6522**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6532**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6507**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

**6523**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

**6535**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

**6502**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required (STREAMLINED)**

**6516**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required (STREAMLINED)**

**6644**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.

**Authority required (STREAMLINED)**

**6673**

Chemotherapy-induced neutropenia

**Clinical criteria:**

HSD (Public)

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).

**Authority required (STREAMLINED)**

**6634**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.

**Authority required (STREAMLINED)**

**6682**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

**Authority required (STREAMLINED)**

**6653**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**6654**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**6657**

Assisting peripheral blood progenitor cell or bone marrow transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10**

5787N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*973.76	Granocyte 13 [PF]

**LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10**

5788P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*2438.84	Granocyte 34 [PF]

▪ **LIPEGFILGRASTIM**

**Authority required (STREAMLINED)**

**6522**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6544**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required (STREAMLINED)**

**6545**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**

- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6532**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6515**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6492**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6507**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

**6533**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required (STREAMLINED)**

**6523**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

**6534**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required (STREAMLINED)**

**6535**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

**6536**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required (STREAMLINED)**

**6493**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

10936N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1250.00	Lonquex [TB]

▪ **PEGFILGRASTIM**

**Authority required (STREAMLINED)**

**6544**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required (STREAMLINED)**

**6522**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6545**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6532**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6515**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6492**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6507**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

**6533**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required (STREAMLINED)**

**6523**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

**6534**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required (STREAMLINED)**

**6535**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

**6536**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required (STREAMLINED)**

**6493**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required (STREAMLINED)**

**6502**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required (STREAMLINED)**

**6516**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

9514R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	1250.00	<sup>a</sup> Neulasta [AN]	<sup>a</sup> Ristempa [GV]

*Interferons*

▪ **INTERFERON ALFA-2A**

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required (STREAMLINED)**

**5042**

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**

- The condition must be Philadelphia chromosome positive.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

5759D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*849.30	Roferon-A [RO]

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

5762G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*2547.30	Roferon-A [RO]

▪ **INTERFERON ALFA-2B**

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required (STREAMLINED)**

**5042**

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**

- The condition must be Philadelphia chromosome positive.

**Authority required (STREAMLINED)**

**4974**

Malignant melanoma

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
- Patient must have undergone surgery, **AND**
- The condition must include nodal involvement.

**interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL**

5765K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1132.02	Intron A Redipen [MK]

**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

5764J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*566.02	Intron A Redipen [MK]

**interferon alfa-2b 18 million units/3 mL injection, 3 mL vial**

5766L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	15	5	..	*2547.00	Intron A [MK]

**interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials**

5768N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*1415.04	Intron A [MK]

**interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial**

5767M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	15	5	..	*3537.60	Intron A [MK]

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

5763H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*339.60	Intron A Redipen [MK]

▪ **INTERFERON GAMMA-1B**

**Authority required (STREAMLINED)**

**6222**

Chronic granulomatous disease

**Clinical criteria:**

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

**interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials**

5769P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*2585.72	Imukin [BY]

▪ **PEGINTERFERON ALFA-2A**

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:  
 (a) a nurse educator/counsellor for patients; and  
 (b) 24-hour access by patients to medical advice; and  
 (c) an established liver clinic.

**Authority required (STREAMLINED)**

**5004**

Chronic hepatitis C infection

**Treatment criteria:**

- Must be treated in an accredited treatment centre.

**Population criteria:**

- Patient must be aged 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

**Clinical criteria:**

- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.  
 Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

9516W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2565.44	Pegasys [RO]

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

9515T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2215.22	Pegasys [RO]

▪ **PEGINTERFERON ALFA-2A**

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

11026H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	1282.72	Pegasys [RO]

*Other immunostimulants*

▪ **PLERIXAFOR**

**Note** Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

**Authority required (STREAMLINED)**

**4549**

Mobilisation of haematopoietic stem cells

**Clinical criteria:**

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; OR
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**plerixafor 24 mg/1.2 mL subcutaneous infusion injection, 1.2 mL vial**

10083Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	6991.00	Mozobil [GZ]

**■ IMMUNOSUPPRESSANTS**  
**IMMUNOSUPPRESSANTS**  
*Selective immunosuppressants*

**■ ABATACEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

#### (2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

#### (3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20

mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

- Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:
- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
  - (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
  - (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:
- Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:
- Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**abatacept 250 mg injection, 1 vial**

5605B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	266.34	Orencia [BQ]

▪ **ALEMTUZUMAB**

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6847**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

10232M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	..	..	*34182.00	Lemtrada [GZ]

▪ **ALEMTUZUMAB**

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6884**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

10228H	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	..	..	*56970.00	Lemtrada [GZ]

■ **ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

**Clinical criteria:**

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for **Initial Treatment**, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma

exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

### eculizumab 300 mg/30 mL injection, 30 mL vial

10190H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	5937.50	Soliris [XI]

#### ■ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than  $30 \times 10^9/L$  and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than  $150 \times 10^9/L$ ; and evidence of two of the following:

- presence of schistocytes on blood film;
- low or absent haptoglobin;
- lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; **AND**

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

- (a) kidney impairment as demonstrated by one of the following:
  - (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
  - (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
  - (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
  - (iv) a renal biopsy consistent with aHUS;
- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application; and
- (7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
- (8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1 - balance of supply**; and
- (9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
- (10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
- (11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10191J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5937.50	Soliris [XI]

▪ **ECULIZUMAB**

- Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.
- Note** For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.
- Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.
- Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
  - a) Active malignancy;
  - b) Active HIV infection;
  - c) Hematopoietic stem cell transplants;
  - d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
  - e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
  - f) Active autoimmune diseases;
 In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.
- Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
  - a) Presenting clinical features, including history, acute treatment and medications;
  - b) Results of testing for genetic mutations (if available);
  - c) Family history of aHUS, especially in first-degree relatives;
  - d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

#### **Clinical criteria:**

- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 56 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10525Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	5937.50	Soliris [XI]

▪ **ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**

- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**

- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

#### **Clinical criteria:**

- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:
  - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
  - b) an eGFR within +/- 25% from baseline; or
  - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease; and
- (11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and
- (12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and
- (13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:

- a) Evidence of a mutation known to confer a high risk of aHUS recurrence;
- b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;
- c) Past family history of aHUS recurrence, especially in first-degree relatives;
- d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

#### **Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count  $<150 \times 10^9/L$ );OR(iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:
  - a) An increase in eGFR of  $> 25\%$  from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
  - b) an eGFR within  $\pm 25\%$  from baseline; or
  - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form(s); and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application, and
- (7) An identified genetic mutation, if applicable; and

- (8) A family history of aHUS if applicable; and
- (9) A history of multiple episodes of aHUS following the treatment break, if applicable; and
- (10) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (11) An inclusion of the individual consequences of recurrent disease; and
- (12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
- (14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

#### **Clinical criteria:**

- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

### eculizumab 300 mg/30 mL injection, 30 mL vial

10183Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	5937.50	Soliris [XI]

### ■ EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

#### **Authority required (STREAMLINED)**

#### **5795**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

#### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

#### **Authority required (STREAMLINED)**

#### **5554**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

#### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

### everolimus 750 microgram tablet, 60

5740D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*2739.44	Certican [NV]

### everolimus 1 mg tablet, 60

5737Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*3652.56	Certican [NV]

### everolimus 500 microgram tablet, 60

5739C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*913.14	Certican [NV]

### everolimus 250 microgram tablet, 60

5738B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*456.58	Certican [NV]

### ■ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

#### **Authority required (STREAMLINED)**

#### **5795**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

#### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

#### **Authority required (STREAMLINED)**

#### **5554**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

#### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

### mycophenolate mofetil 500 mg tablet, 50

9502D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*263.76	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Ceptolate [AF] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> CellCept [RO] <sup>a</sup> Mycophenolate AN [EA] <sup>a</sup> Pharmacor Mycophenolate 500 [CR]

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

9500B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*489.02	CellCept [RO]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Note** Management includes initiation, stabilisation and review of therapy as required.

**Authority required (STREAMLINED)**

**4084**

Prophylaxis of renal allograft rejection

Treatment Phase: Management

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**4095**

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

**Clinical criteria:**

- The condition must be proven by biopsy.

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.  
The name of the consulting nephrologist must be included in the patient medical records.

**mycophenolate 360 mg enteric tablet, 120**

9504F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*343.12	Myfortic [NV]

**mycophenolate 180 mg enteric tablet, 120**

9503E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*171.58	Myfortic [NV]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution

**Authority required (STREAMLINED)**

**5653**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**5600**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 250 mg capsule, 100**

9501C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*263.88	<sup>a</sup> APO-Mycophenolate [TX]	<sup>a</sup> CellCept [RO]
					<sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> Pharmacor Mycophenolate 250 [CR]

**mycophenolate Capsule 250 mg, 50**

1839T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	12	5	..	*263.88	<sup>a</sup> Ceptolate [AF]

▪ **NATALIZUMAB**

**Caution** Progressive multifocal leukoencephalopathy has been reported with this drug.

**Authority required (STREAMLINED)**

**6875**

Clinically definite relapsing-remitting multiple sclerosis

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

**Population criteria:**

- Patient must be aged 18 years or older.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**natalizumab 300 mg/15 mL injection, 15 mL vial**

9505G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1489.64	Tysabri [BD]

**■ SIROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)****5795**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**sirolimus 1 mg tablet, 100**

9549N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1374.32	Rapamune [PF]

**sirolimus 2 mg tablet, 100**

9548M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2748.68	Rapamune [PF]

**sirolimus 1 mg/mL oral liquid, 60 mL**

9550P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*889.20	Rapamune [PF]

**sirolimus 500 microgram tablet, 100**

9747B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*687.18	Rapamune [PF]

**■ VEDOLIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

- (i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient – Initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for adalimumab, infliximab or vedolizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction), **AND**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment (Grandfather patient)

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, **AND**
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic baseline assessment is not available, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be 18 years of age or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and baseline Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the date of commencement of this drug; and
  - (iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** The patient must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**vedolizumab 300 mg injection, 1 vial**

10384M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3105.19	Entyvio [TK]

▪ **VEDOLIZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
 Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Adalimumab only:** Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Ustekinumab only:** Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient – initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iv) the date of the most recent clinical assessment; and
  - (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

**Note** This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
  - (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
  - (iii) the date of clinical assessment; and
  - (iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iv) the date of the most recent clinical assessment; and
  - (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

#### **Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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#### **Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

### vedolizumab 300 mg injection, 1 vial

10390W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3105.19	Entyvio [TK]

### Tumor necrosis factor alpha (TNF-) inhibitors

#### ▪ ADALIMUMAB

##### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

##### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

##### **Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

##### **Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than

12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**

- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9663N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1279.86	Humira [VE]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9662M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1279.86	Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

9661L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1279.86	Humira [VE]

▪ **ETANERCEPT**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum

of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to

respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline

measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

5733R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	939.25	Enbrel [PF]

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

5735W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	939.25	Enbrel [PF]

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

5734T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	469.63	Enbrel [PF]

▪ **INFLIXIMAB**

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**4524**

Acute severe ulcerative colitis

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

**Clinical criteria:**

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**infliximab 100 mg injection, 1 vial**

10067W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	..	*2537.10	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

■ **INFLIXIMAB**

**Note** Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au).

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia  
 Prior Written Approval of Specialised Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare

Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

### **Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and  
(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

The authority application must be made in writing

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
  - (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

The authority application must be made in writing

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

- (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
- (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) is receiving treatment with infliximab at the time of application; and
- (e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:
  - (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
  - (ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

The authority application must be made in writing

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

The authority application must be made in writing

**infliximab 100 mg injection, 1 vial**

9654D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients

with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in

terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF- $\alpha$  antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF- $\alpha$  antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF- $\alpha$  antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of

this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)).

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

- a completed authority prescription form; and
- a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:
  - the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
  - details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response

assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### **Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the 'Balance of Supply' treatment phase PBS restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for a paediatric patient

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 3 doses or 2 repeats.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

5755X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - the date of the most recent clinical assessment; and
  - the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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#### **Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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#### **Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

**infliximab 100 mg injection, 1 vial**

5754W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

## ■ INFLIXIMAB

### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

- (i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- $\alpha$  antagonist. For second and subsequent courses of PBS-subsidised TNF- $\alpha$  antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate agent at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time

other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF- $\alpha$  antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured. (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Re commencement of treatment after more than 5 years break in therapy - Initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

#### **Population criteria:**

- Patient must be 6 years of age or older.

Applications for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the signed patient acknowledgement or guardian acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

The authority application must be made in writing

Up to a maximum of 2 repeats will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug. Applications for authorisation of initial treatment must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy];

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction).

**Population criteria:**

- Patient must be 6 years of age or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**infliximab 100 mg injection, 1 vial**

10196P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

#### **Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

#### **Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing

Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
  - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
  - (ii) a completed BASDAI Assessment Form; and
  - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
  - (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

#### **Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

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### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.  
 A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.  
 At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.  
 All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.  
 Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
 Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Ankylosing spondylitis  
 Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

5753T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and

who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

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#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with infliximab, **AND**
- Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

5757B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

## ■ INFLIXIMAB

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

#### (3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

#### (4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of

the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

#### **Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5

years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

#### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be an adult.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
 Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### **Population criteria:**

- Patient must be an adult.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

5756Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
- (iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where applicable an application is submitted to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services where required, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Response to treatment will be determined based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

### **Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

5758C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

*Interleukin inhibitors*

▪ **ANAKINRA**

**Note** This drug is not PBS-subsidised for conditions other than CAPS.

**Authority required (STREAMLINED)**

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

**Treatment criteria:**

- Must be treated by a rheumatologist or in consultation with a rheumatologist; OR
- Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

**anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes**

10264F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1650.00	Kineret [FK]

▪ **TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability

arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately

prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

10077J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	102.74	Actemra [RO]

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

10056G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	254.66	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

10064Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	506.74	Actemra [RO]

**■ TOCILIZUMAB**
**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis  
Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

10081N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	102.74	Actemra [RO]

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

10058J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	254.66	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

10072D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	506.74	Actemra [RO]

**■ TOCILIZUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Abatacept patients:** Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

**Rituximab patients:** A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. **Rituximab patients:** A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

**Abatacept:** Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

**Rituximab:** In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**

- Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
 Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis  
 Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

9657G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	102.74	Actemra [RO]

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

9658H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	254.66	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

9659J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	506.74	Actemra [RO]

▪ **TOCILIZUMAB**

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or
- (iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).

months (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.

(4) Commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

#### **Clinical criteria:**

- Patient must have been diagnosed with systemic juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR
- Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
  - (ii) details of prior treatment including dose and duration of treatment;
  - (iii) pathology reports detailing CRP and platelet count where appropriate; and
  - (3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

**Note** Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

#### **Clinical criteria:**

- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, **AND**
- Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or commencement of treatment after a break of less than 12 months) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Initial 2 (retrial or commencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

1476Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	102.74	Actemra [RO]

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

1481Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	254.66	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

1482B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	506.74	Actemra [RO]

▪ **USTEKINUMAB**

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Adalimumab only:** Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Ustekinumab only:** Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

## **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

## **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

## **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

## **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**ustekinumab 130 mg/26 mL injection, 26 mL vial**

11182M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*16929.24	Stelara [JC]

*Calcineurin inhibitors*

▪ **CYCLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**6628**

Management of transplant rejection

**Clinical criteria:**

- The treatment must be used by organ or tissue transplant recipients.

**cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules**

5631J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	54.10	Sandimmun [NV]

▪ **CYCLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**6643**

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**6660**

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologists.

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

**Authority required (STREAMLINED)**

**6676**

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Authority required (STREAMLINED)**

**6631**

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

**Treatment criteria:**

- Must be treated by a nephrologist.

**Authority required (STREAMLINED)**

**6638**

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

**cyclosporin 100 mg/mL oral liquid, 50 mL**

5633L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	4	5	..	*1263.16	Neoral [NV]	

**cyclosporin 25 mg capsule, 30**

5634M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*128.88	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 25 [NV]

**cyclosporin 10 mg capsule, 60**

5632K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	2	5	..	*74.40	Neoral 10 [NV]	

**cyclosporin 50 mg capsule, 30**

5635N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*268.16	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 50 [NV]

**cyclosporin 100 mg capsule, 30**

5636P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*546.40	<sup>a</sup> Cyclosporin Sandoz [SZ]	<sup>a</sup> Neoral 100 [NV]

▪ **TACROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**5569**

Management of rejection in patients following organ or tissue transplantation

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

**tacrolimus 1 mg modified release capsule, 60**

9665Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*263.28	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

**tacrolimus 2 mg capsule, 100**

10860N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	2	5	..	*1000.00	Tacrolimus Sandoz [SZ]	

**tacrolimus 5 mg modified release capsule, 30**

9666R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*750.44	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

**tacrolimus 500 microgram modified release capsule, 30**

9664P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*75.04	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Prograf XL [LL]

**tacrolimus 500 microgram capsule, 100**

9558C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*219.40	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 0.5 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

**tacrolimus 5 mg capsule, 50**

9561F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1096.44	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 5 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

**tacrolimus 750 microgram capsule, 100**

10859M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	2	5	..	*375.00	Tacrolimus Sandoz [SZ]	

**tacrolimus 1 mg capsule, 100**

9560E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*438.80	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL]	<sup>a</sup> Pharmacor Tacrolimus 1 [CR] <sup>a</sup> TACROLIMUS APOTEX [TX]

**Other immunosuppressants****▪ LENALIDOMIDE**

**Note** Special Pricing Arrangements apply.

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
- (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (d) a copy of the full blood examination report; and
- (e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
- (f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
- (g) a signed patient acknowledgement form.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

- (i) a haemoglobin level taken within the last 4 weeks; and

- (ii) the date of the last transfusion; and
- (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and
- (iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**lenalidomide 5 mg capsule, 21**

2799H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5122.76	Revlimid [CJ]

**lenalidomide 10 mg capsule, 21**

2802L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5361.16	Revlimid [CJ]

▪ **LENALIDOMIDE**

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or

- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

- (1) less than a 25% reduction in serum or urine M protein; or
- (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**

- Patient must have previously received an authority prescription for lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**lenalidomide 15 mg capsule, 21**

5785L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6252.53	Revlimid [CJ]

**lenalidomide 5 mg capsule, 21**

5783J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5122.76	Revlimid [CJ]

**lenalidomide 25 mg capsule, 21**

5786M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6587.49	Revlimid [CJ]

**lenalidomide 10 mg capsule, 21**

5784K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5361.16	Revlimid [CJ]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and
- (3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Patient must be registered in the i-access risk management program.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**lenalidomide 15 mg capsule, 21**

11062F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6252.53	Revlimid [CJ]

**lenalidomide 5 mg capsule, 21**

11029L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5122.76	Revlimid [CJ]

**lenalidomide 25 mg capsule, 21**

11041D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6587.49	Revlimid [CJ]

**lenalidomide 10 mg capsule, 21**

11064H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5361.16	Revlimid [CJ]

▪ **POMALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and

(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**pomalidomide 4 mg capsule, 21**

10387Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10500.00	Pomalyst [CJ]

**pomalidomide 3 mg capsule, 21**

10406Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10500.00	Pomalyst [CJ]

▪ **RITUXIMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised

therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab: In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised bDMARD during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs

specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**rituximab 500 mg/50 mL injection, 50 mL vial**

9544H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1864.22	Mabthera [RO]

HSD (Public)

# MUSCULO-SKELETAL SYSTEM

## ▪ THALIDOMIDE

**Caution** Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

**Authority required (STREAMLINED)**

**5914**

Multiple myeloma

### thalidomide 100 mg capsule, 28

9667T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1596.00	Thalomid [CJ]

### thalidomide 50 mg capsule, 28

9566L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*1596.00	Thalomid [CJ]

## ▪ MUSCULO-SKELETAL SYSTEM

### ▪ MUSCLE RELAXANTS

#### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

##### *Other centrally acting agents*

## ▪ BACLOFEN

**Authority required (STREAMLINED)**

**7152**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

**Authority required (STREAMLINED)**

**7134**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**

**7153**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**

**7148**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

### baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule

11195F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*996.80	Sintetica Baclofen Intrathecal [BZ]

## ▪ BACLOFEN

**Note** Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**6925**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**

- Patient must have chronic spasticity of cerebral origin.

**Authority required (STREAMLINED)**

**6939**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**

**6940**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**

**6911**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

**baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule**

5617P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*1246.30	<sup>a</sup> Bacthecal [DZ]	<sup>a</sup> Lioresal Intrathecal [NV]

**baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules**

11126N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1246.30	<sup>a</sup> Sintetica Baclofen Intrathecal [BZ]

**DRUGS FOR TREATMENT OF BONE DISEASES**

**DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION**

*Bisphosphonates*

**IBANDRONATE**

**Authority required (STREAMLINED)**

**5291**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**ibandronate 6 mg/6 mL injection, 6 mL vial**

5750P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	324.29	Bondronat [RO]

**PAMIDRONATE DISODIUM**

**Authority required (STREAMLINED)**

**4433**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**pamidronate disodium 60 mg/10 mL injection, 10 mL vial**

5669J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	55.26	Pamisol [PF]

**pamidronate disodium 15 mg/5 mL injection, 5 mL vial**

5667G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	2	..	*55.24	Pamisol [PF]

**pamidronate disodium 30 mg/10 mL injection, 10 mL vial**

5668H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*55.26	Pamisol [PF]

▪ PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**

**4433**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**Authority required (STREAMLINED)**

**5218**

Multiple myeloma

**Authority required (STREAMLINED)**

**5291**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**pamidronate disodium 90 mg/10 mL injection, 10 mL vial**

5670K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	82.89	Pamisol [PF]

▪ ZOLEDRONIC ACID

**Note** Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**5735**

Multiple myeloma

**Authority required (STREAMLINED)**

**5605**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Authority required (STREAMLINED)**

**5703**

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.

**Authority required (STREAMLINED)**

**5704**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**zoledronic acid 4 mg/100 mL injection, 100 mL bag**

10561W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	245.33	<sup>a</sup> DBL Zoledronic Acid [PF]

**zoledronic acid 4 mg/100 mL injection, 100 mL vial**

10548E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	245.33	<sup>a</sup> Zometa [NV]

**zoledronic acid 4 mg/5 mL injection, 5 mL vial**

9653C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	245.33	<sup>a</sup> APO-Zoledronic Acid [TX] <sup>a</sup> Zometa [NV]	<sup>a</sup> DBL Zoledronic Acid [PF]

▪ NERVOUS SYSTEM

▪ ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

*Dopa and dopa derivatives*

▪ LEVODOPA + CARBIDOPA ANHYDROUS

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required (STREAMLINED)**

**6863**

Advanced Parkinson disease

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

9743T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11536.00	Duodopa [VE]

*Dopamine agonists*■ **APOMORPHINE****Authority required (STREAMLINED)****6813**

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**apomorphine hydrochloride 100 mg/20 mL injection, 5 x 20 mL vials**

11093W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	5	..	*7552.80	Apomine Solution for Infusion [PF]

■ **APOMORPHINE****Authority required (STREAMLINED)****4833**

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules**

5610G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8168.04	Movapo [TD]

**apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules**

5609F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	72	5	..	*6528.96	Movapo [TD]

**apomorphine hydrochloride 50 mg/10 mL injection, 5 x 10 mL syringes**

10950H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8168.04	Movapo PFS [TD]

■ **PSYCHOLEPTICS****ANTIPSYCHOTICS***Diazepines, oxazepines, thiazepines and oxepines*■ **CLOZAPINE**

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

**Authority required (STREAMLINED)****5015**

Schizophrenia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

**Clinical criteria:**

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

**clozapine 200 mg tablet, 100**

5627E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*484.76	Clopine 200 [PF]

## RESPIRATORY SYSTEM

### clozapine 100 mg tablet, 100

5629G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*242.38	<sup>a</sup> Clopine 100 [PF]	<sup>a</sup> Clozaril 100 [NV]

### clozapine 25 mg tablet, 100

5628F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*64.64	<sup>a</sup> Clopine 25 [PF]	<sup>a</sup> Clozaril 25 [NV]

### clozapine 50 mg tablet, 100

5626D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*129.28	Clopine 50 [PF]

### clozapine 50 mg/mL oral liquid, 100 mL

5630H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	135.00	Clopine Suspension [PF]

## RESPIRATORY SYSTEM

## DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

*Other systemic drugs for obstructive airway diseases*

#### MEPOLIZUMAB

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
- A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
- A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

## (c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

## (2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

## (3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 6 weeks, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

- Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
- treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, **OR** a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, **OR** 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current

treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
  - (iii) the signed patient or parent/guardian acknowledgement; and
- (c) a copy of the eosinophil pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**mepolizumab 100 mg injection, 1 vial**

10996R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	1638.00	Nucala [GK]

▪ **MEPOLIZUMAB**

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA**  
 Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
- iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant

exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to mepolizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with mepolizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 26 to 30 weeks after the first dose of PBS-subsidised mepolizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with mepolizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** It is recommended that second and subsequent applications for continuing treatment are submitted at the time of an 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment - grandfather patients

#### **Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of mepolizumab, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**

- Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of mepolizumab, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of mepolizumab, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to mepolizumab therapy despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with mepolizumab, **AND**
- The treatment must not be used in combination with omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

- Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
  - treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, **OR** a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-mepolizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with mepolizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:
  - details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
  - details of pre- and post-mepolizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and
  - the signed patient or parent/guardian acknowledgement; and
  - a copy of the pre-mepolizumab eosinophil pathology report.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or

www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### mepolizumab 100 mg injection, 1 vial

10980X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1638.00	Nucala [GK]

### ■ OMALIZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

#### **Clinical criteria:**

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

- 1) a H2 receptor antagonist (150 mg twice per day); or
- 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
- 3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:
  - (i) demonstration of failure to achieve an adequate response to standard therapy; and
  - (ii) drug names and doses of standard therapies that the patient has failed; and
  - (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

### omalizumab 150 mg/mL injection, 1 mL syringe

11176F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*820.00	Xolair [NV]

### ■ OMALIZUMAB

#### Authority required

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

#### **Clinical criteria:**

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

**Note** A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note** Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe chronic spontaneous urticaria  
Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- Patient must have documented history of itch and hives that persisted on a daily basis for at least 6 weeks despite treatment with H1 antihistamines prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have documented history of failure to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:  
1) a H2 receptor antagonist (150 mg twice per day); or  
2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or  
3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial Grandfather PBS Authority Application - Supporting Information Form which must include:
  - (i) demonstration of failure to achieve an adequate response to standard therapy; and
  - (ii) drug names and doses of standard therapies that the patient has failed; and
  - (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**omalizumab 150 mg/mL injection, 1 mL syringe**

11168T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*820.00	Xolair [NV]

▪ **OMALIZUMAB**

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma  
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV<sub>1</sub>) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to less than 12 years.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; **AND**

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), **AND**

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) acknowledgement signed by a parent or authorised guardian; and

(c) a copy of the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the prescriber's signature.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR
- (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial and continuing treatment - balance of supply

### **Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction or Grandfather treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing or Grandfather restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing or grandfather restrictions may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Grandfather patients

### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of omalizumab, a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of omalizumab, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to omalizumab therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated an adequate response to treatment.

### **Population criteria:**

- Patient must be aged 6 to less than 12 years.

### **Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

- (i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND
- (ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

- (i) a reduction in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire Interviewer Administered (ACQ-IA) score of at least 0.5;
- (ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or
- (iii) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

Patients will be eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for an initial course of omalizumab of up to 24 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Grandfather Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
  - (ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and
  - (iii) acknowledgement signed by a parent or authorised guardian.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

- (1) How to prescribe PBS-subsidised omalizumab therapy.

## (a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

## (b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

## (c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

## (2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

## (3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

## (4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**omalizumab 150 mg/mL injection, 1 mL syringe**

10973M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	410.00	Xolair [NV]

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

10967F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	205.00	Xolair [NV]

**■ OMALIZUMAB**

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**

- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
  - (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, **OR** a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
  - (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, **OR** 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.
- The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
  - (iii) the signed patient or parent/guardian acknowledgement; and
- (c) the IgE pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
- iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, OR
- (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose, and the assessment of time adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber; for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
- iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of

therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **omalizumab 150 mg/mL injection, 1 mL syringe**

10109C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	410.00	Xolair [NV]

### **omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

10118M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	205.00	Xolair [NV]

## ■ COUGH AND COLD PREPARATIONS

### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

#### *Mucolytics*

#### ■ DORNASE ALFA

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

#### **Authority required (STREAMLINED)**

**5740**

Cystic fibrosis

#### **Population criteria:**

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required (STREAMLINED)**

**5634**

Cystic fibrosis

**Clinical criteria:**

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required (STREAMLINED)**

**5635**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

5704F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2242.00	Pulmozyme [RO]

▪ **MANNITOL**

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required (STREAMLINED)**

**5799**

Cystic fibrosis

**Clinical criteria:**

- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

**Population criteria:**

- Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND  
 (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

### MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1

2015C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1736.00	bronchitol [XA]

## OTHER RESPIRATORY SYSTEM PRODUCTS

### OTHER RESPIRATORY SYSTEM PRODUCTS

*Other respiratory system products*

#### ■ IVACAFTOR

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

#### Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

#### **Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

#### **Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
- (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
- (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older.

Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

- (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (7) a copy of a sweat chloride result; and
- (8) height and weight measurements at the time of application; and
- (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
- (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (5) height and weight measurements at the time of application; and
- (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

**ivacaftor 150 mg tablet, 56**

10170G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22500.00	Kalydeco [VR]

**■ IVACAFTOR****Note** Special Pricing Arrangements apply.**Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
- (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
- (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (7) a copy of a sweat chloride result; and
- (8) height and weight measurements at the time of application; and
- (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem,

erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
  - (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
  - (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older.
- Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
  - (5) height and weight measurements at the time of application; and
  - (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

#### **Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have received treatment with ivacaftor for this condition prior to 1 May 2017, **AND**
- Patient must have received treatment with ivacaftor within the last 6 months at the time of application, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

#### **Population criteria:**

- Patient must be 2 to 5 years of age.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
- (3) an acknowledgement signed by a parent, or authorised guardian if applicable; and

- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
- (5) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (6) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
- (7) height and weight measurements at the time of application; and
- (8) height and weight measurements performed immediately prior to commencement of ivacaftor; and
- (9) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
- (10) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and
- (11) dates of prior ivacaftor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

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Reply Paid 9826

HOBART TAS 7001

**ivacaftor 75 mg granules, 4 x 14 sachets**

11098D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22500.00	Kalydeco [VR]

**ivacaftor 50 mg granules, 4 x 14 sachets**

11105L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22500.00	Kalydeco [VR]

**VARIOUS**  
**ALL OTHER THERAPEUTIC PRODUCTS**  
**ALL OTHER THERAPEUTIC PRODUCTS**  
*Iron chelating agents*

▪ **DEFERASIROX**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6420**

Chronic iron overload

**Clinical criteria:**

- Patient must have a disorder of erythropoiesis.

**deferasirox 500 mg dispersible tablet, 28**

5656Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*5325.54	Exjade [NV]

**deferasirox 125 mg dispersible tablet, 28**

5654N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*1331.40	Exjade [NV]

**deferasirox 250 mg dispersible tablet, 28**

5655P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2662.74	Exjade [NV]

▪ **DEFERIPRONE**

**Authority required (STREAMLINED)**

**6448**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

**Authority required (STREAMLINED)**

**6403**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

**deferiprone 500 mg tablet, 100**

5657R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2568.18	Feriprox [TX]

**deferiprone 100 mg/mL oral liquid, 250 mL**

5658T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	5	..	*1070.10	Feriprox [TX]

**▪ DEFERRIOXAMINE****Authority required (STREAMLINED)****6394**

Disorders of erythropoiesis

**Clinical criteria:**

- The condition must be associated with treatment-related chronic iron overload.

**desferrioxamine mesilate 2 g injection, 1 vial**

5661Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	60	5	..	*1868.40	Hospira Pty Limited [PF]

**desferrioxamine mesilate 500 mg injection, 10 vials**

5662B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	40	5	..	*4254.80	Hospira Pty Limited [PF]

***Drugs for treatment of hyperkalemia and hyperphosphatemia*****▪ LANTHANUM****Authority required (STREAMLINED)****5530**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**

5782H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*845.52	Fosrenol [ZI]

**LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**

5780F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*497.36	Fosrenol [ZI]

**LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**

5781G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*751.04	Fosrenol [ZI]

**▪ SEVELAMER****Authority required (STREAMLINED)****5530**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

## VARIOUS

### sevelamer hydrochloride 800 mg tablet, 180

9546K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*589.00	Renagel [GZ]

### ▪ SUCROFERRIC OXYHYDROXIDE

#### Authority required (STREAMLINED)

**5530**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

#### **Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

#### **Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

### iron (as sucroferic oxyhydroxide) 500 mg tablet: chewable, 90

10233N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*753.46	Velphoro [FN]

HSD (Public)

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# Highly Specialised Drugs Program (Community Access)

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ANTIINFECTIVES FOR SYSTEMIC USE .....	1240
ANTIVIRALS FOR SYSTEMIC USE .....	1240
DIRECT ACTING ANTIVIRALS .....	1240
<hr/>	
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	1257
IMMUNOSTIMULANTS .....	1257
IMMUNOSTIMULANTS .....	1257
<hr/>	
NERVOUS SYSTEM.....	1259
PSYCHOLEPTICS.....	1259
ANTIPSYCHOTICS.....	1259

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

GANCICLOVIR

**Authority required (STREAMLINED)**

**5000**

Cytomegalovirus retinitis

**Clinical criteria:**

- Patient must be severely immunocompromised, including due to HIV infection.

**ganciclovir 500 mg injection, 5 vials**

10328N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*560.43	38.80	Cymevene [RO]

VALGANCICLOVIR

**Authority required (STREAMLINED)**

**4980**

Cytomegalovirus retinitis

**Clinical criteria:**

- Patient must have HIV infection.

**valganciclovir 50 mg/mL powder for oral liquid, 100 mL**

10277X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	11	5	..	*#4396.02	38.80	Valcyte [RO]

**valganciclovir 450 mg tablet, 60**

10306K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*3631.45	38.80	<sup>a</sup> Valcyte [RO] <sup>a</sup> Valganciclovir Juno [JU] <sup>a</sup> Valganciclovir Sandoz [SZ]	<sup>a</sup> Valganciclovir AN [EA] <sup>a</sup> Valganciclovir Mylan [AF]

*Protease inhibitors*

ATAZANAVIR

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**atazanavir 150 mg capsule, 60**

10276W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1038.43	38.80	Reyataz [BQ]

**atazanavir 300 mg capsule, 30**

10321F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1038.43	38.80	Reyataz [BQ]

**atazanavir 200 mg capsule, 60**

10349Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1369.33	38.80	Reyataz [BQ]

ATAZANAVIR + COBICISTAT

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**atazanavir 300 mg + cobicistat 150 mg tablet, 30**

10692R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1116.57	38.80	Evotaz [BQ]

**▪ DARUNAVIR****Authority required (STREAMLINED)****5094**

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**darunavir 150 mg tablet, 240**

10287K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	877.49	38.80	Prezista [JC]

**▪ DARUNAVIR**

**Note** Pharmaceutical benefits that have the form darunavir tablet 600 mg and pharmaceutical benefits that have the form darunavir tablet 600 mg (as ethanolate) are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****5094**

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**darunavir 600 mg tablet, 60**

10329P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1720.89	38.80	<sup>a</sup> Prezista [JC]

**darunavir 600 mg tablet, 60**

11214F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1720.89	38.80	<sup>a</sup> Darunavir Mylan [AF]

**▪ DARUNAVIR**

**Note** Pharmaceutical benefits that have the form darunavir tablet 800 mg and pharmaceutical benefits that have the form darunavir tablet 800 mg (as ethanolate) are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****4313**

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**

## ANTIINFECTIVES FOR SYSTEMIC USE

- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
- Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

### darunavir 800 mg tablet, 30

10367P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1162.97	38.80	<sup>a</sup> Prezista [JC]

### darunavir 800 mg tablet, 30

11203P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1162.97	38.80	<sup>a</sup> Darunavir Mylan [AF]

## ▪ FOSAMPRENAVIR

### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### fosamprenavir 700 mg tablet, 60

10337C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*756.37	38.80	Telzir [VI]

## ▪ INDINAVIR

### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### indinavir 400 mg capsule, 180

10363K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*906.23	38.80	Crixivan 400 mg [MK]

## ▪ RITONAVIR

### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Authority required (STREAMLINED)

**4454**

HIV infection  
Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**ritonavir 100 mg tablet, 30**

10273Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	24	5	..	*978.19	38.80	Norvir [VE]

**ritonavir 600 mg/7.5 mL oral liquid, 90 mL**

10300D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	5	..	*906.25	38.80	Norvir [VE]

▪ **SAQUINAVIR**

**Authority required (STREAMLINED)**

**4512**

HIV infection  
Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection  
Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**saquinavir 500 mg tablet, 120**

10335Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1006.13	38.80	Invirase [RO]

▪ **TIPRANAVIR**

**Authority required (STREAMLINED)**

**5764**

HIV infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- The treatment must be co-administered with 200 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**tipranavir 250 mg capsule, 120**

10344K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1675.07	38.80	Aptivus [BY]

***Nucleoside and nucleotide reverse transcriptase inhibitors***

▪ **ABACAVIR**

**Authority required (STREAMLINED)**

**4512**

HIV infection  
Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection  
Treatment Phase: Continuing

**Clinical criteria:**

## ANTIINFECTIVES FOR SYSTEMIC USE

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### abacavir 300 mg tablet, 60

10294T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*564.39	38.80	Ziagen [VI]

### abacavir 20 mg/mL oral liquid, 240 mL

10356C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*656.35	38.80	Ziagen [VI]

## ■ ADEFOVIR DIPIVOXIL

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

### Authority required (STREAMLINED)

**4490**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

### Authority required (STREAMLINED)

**4510**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

### adefovir dipivoxil 10 mg tablet, 30

10290N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1097.15	38.80	<sup>a</sup> APO-Adefovir [TX]	<sup>a</sup> Hepsera [GI]

## ■ DIDANOSINE

### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### didanosine 400 mg enteric capsule, 30

10313T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*652.89	38.80	Videx EC [BQ]

### didanosine 250 mg enteric capsule, 30

10364L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*410.73	38.80	Videx EC [BQ]

## ■ EMTRICITABINE

### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**emtricitabine 200 mg capsule, 30**

10274R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*564.39	38.80	Emtriva [GI]

▪ **ENTECAVIR**

**Authority required (STREAMLINED)**

**4993**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

**Authority required (STREAMLINED)**

**5036**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
  - Patient must have detectable HBV DNA.
- Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**entecavir monohydrate 500 microgram tablet, 30**

10279B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*645.05	38.80	<sup>a</sup> Baraclude [BQ] <sup>a</sup> Entecavir Amneal [EA] <sup>a</sup> Entecavir GH [GQ] <sup>a</sup> ENTECAVIR RBX [RA] <sup>a</sup> ENTECLUDE [RW]	<sup>a</sup> ENTAC [LR] <sup>a</sup> Entecavir APOTEX [TX] <sup>a</sup> Entecavir Mylan [AF] <sup>a</sup> Entecavir Sandoz [SZ]

▪ **ENTECAVIR**

**Note** PBS-subsidised entecavir monohydrate must be used as monotherapy.

**Authority required (STREAMLINED)**

**5044**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Authority required (STREAMLINED)**

**5037**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have detectable HBV DNA.

## ANTIINFECTIVES FOR SYSTEMIC USE

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

### entecavir monohydrate 1 mg tablet, 30

10353X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1044.55	38.80	<sup>a</sup> Baraclude [BQ] <sup>a</sup> Entecavir Amneal [EA] <sup>a</sup> Entecavir GH [GQ] <sup>a</sup> ENTECAVIR RBX [RA] <sup>a</sup> ENTECLUDE [RW]	<sup>a</sup> ENTAC [LR] <sup>a</sup> Entecavir APOTEX [TX] <sup>a</sup> Entecavir Mylan [AF] <sup>a</sup> Entecavir Sandoz [SZ]

### ▪ LAMIVUDINE

#### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

#### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### lamivudine 10 mg/mL oral liquid, 240 mL

10320E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*472.91	38.80	3TC [VI]

### lamivudine 150 mg tablet, 60

10348P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*143.41	38.80	<sup>a</sup> 3TC [VI]	<sup>a</sup> Lamivudine Alphapharm [AF]

### lamivudine 300 mg tablet, 30

10311Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*143.41	38.80	<sup>a</sup> 3TC [VI]	<sup>a</sup> Lamivudine Alphapharm [AF]

### ▪ LAMIVUDINE

#### Authority required (STREAMLINED)

**4993**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

#### Authority required (STREAMLINED)

**5036**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

### lamivudine 100 mg tablet, 28

10315X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*80.55	38.80	<sup>a</sup> Zetlam [AF]
			<sup>B</sup> 1.20	*81.75	38.80	<sup>a</sup> Zeffix [RW]

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**lamivudine 5 mg/mL oral liquid, 240 mL**

10338D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*242.45	38.80	Zeffix [RW]

**■ STAVUDINE****Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**stavudine 30 mg capsule, 60**

10271N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*666.51	38.80	Zerit [BQ]

**stavudine 40 mg capsule, 60**

10312R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*886.29	38.80	Zerit [BQ]

**■ TENOFOVIR**

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****6998**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****6982**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****6980**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)****6992**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

## ANTIINFECTIVES FOR SYSTEMIC USE

- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

### **Authority required (STREAMLINED)**

**6983**

Chronic hepatitis B infection

#### **Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

### **Authority required (STREAMLINED)**

**6984**

Chronic hepatitis B infection

#### **Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

### **tenofovir disoproxil fumarate 300 mg tablet, 30**

10310P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*809.03	38.80	<sup>a</sup> Viread [GI]

### **tenofovir disoproxil maleate 300 mg tablet, 30**

11155D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*809.03	38.80	<sup>a</sup> Tenofovir Disoproxil Mylan [AF]

### **tenofovir disoproxil phosphate 291 mg tablet, 30**

11142K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*809.03	38.80	<sup>a</sup> Tenofovir GH [GQ]

## ▪ ZIDOVUDINE

### **Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

#### **Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### **Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### **zidovudine 50 mg/5 mL oral liquid, 200 mL**

10361H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15	5	..	*672.40	38.80	Retrovir [VI]

### **zidovudine 100 mg capsule, 100**

10266H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*819.15	38.80	Retrovir [VI]

## zidovudine 250 mg capsule, 40

10360G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*1218.31	38.80	Retrovir [VI]

### Non-nucleoside reverse transcriptase inhibitors

#### ▪ EFAVIRENZ

##### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

##### **Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

##### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

## efavirenz 30 mg/mL oral liquid, 180 mL

10275T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	7	5	..	*570.65	38.80	Stocrin [MK]

## efavirenz 200 mg tablet, 90

10336B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*543.79	38.80	Stocrin [MK]

## efavirenz 600 mg tablet, 30

10366N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*543.79	38.80	Stocrin [MK]

#### ▪ ETRAVIRINE

##### Authority required (STREAMLINED)

**5014**

HIV infection

##### **Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

## etravirine 200 mg tablet, 60

10301E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1218.51	38.80	Intelence [JC]

#### ▪ NEVIRAPINE

##### Authority required (STREAMLINED)

**4526**

HIV infection

Treatment Phase: Initial

##### **Clinical criteria:**

- Patient must have been stabilised on nevirapine immediate release, **AND**
- The treatment must be in combination with other antiretroviral agents.

##### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

## ANTIINFECTIVES FOR SYSTEMIC USE

### nevirapine 400 mg modified release tablet, 30

10303G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*334.01	38.80	<sup>a</sup> Nevirapine XR APOTEX [TX]	<sup>a</sup> Viramune XR [BY]

#### ■ NEVIRAPINE

##### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

##### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

##### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

##### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### nevirapine 10 mg/mL oral liquid, 240 mL

10319D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	5	..	*1397.15	38.80	Viramune [BY]

### nevirapine 200 mg tablet, 60

10304H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*334.01	38.80	<sup>a</sup> Nevirapine Alphapharm [AF]	<sup>a</sup> Viramune [BY]

#### ■ RILPIVIRINE

##### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

##### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

##### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

##### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### rilpivirine 25 mg tablet, 30

10298B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*543.79	38.80	Edurant [JC]

### *Antivirals for treatment of HIV infections, combinations*

#### ■ ABACAVIR + LAMIVUDINE

##### Authority required (STREAMLINED)

**4527**

HIV infection

Treatment Phase: Initial

##### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

##### Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

##### Authority required (STREAMLINED)

**4528**

HIV infection

Treatment Phase: Continuing

##### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**abacavir 600 mg + lamivudine 300 mg tablet, 30**

10357D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*700.65	38.80	Kivexa [VI]

▪ **ABACAIVR + LAMIVUDINE + ZIDOVUDINE**

**Authority required (STREAMLINED)**

**4495**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**Authority required (STREAMLINED)**

**4480**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60**

10305J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1123.43	38.80	Trizivir [VI]

▪ **DARUNAVIR + COBICISTAT**

**Authority required (STREAMLINED)**

**6413**

Human immunodeficiency virus (HIV) infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**Authority required (STREAMLINED)**

**6428**

Human immunodeficiency virus (HIV) infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**Authority required (STREAMLINED)**

**6377**

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

## ANTIINFECTIVES FOR SYSTEMIC USE

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

### darunavir 800 mg + cobicistat 150 mg tablet, 30

10903W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1203.51	38.80	Prezcobix [JC]

### ▪ DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE

#### Authority required (STREAMLINED)

**4495**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive.

#### Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

#### Authority required (STREAMLINED)

**4480**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

#### Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

### dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30

10345L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1928.55	38.80	Triumeq [VI]

### ▪ EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE

#### Authority required (STREAMLINED)

**4522**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive.

#### Authority required (STREAMLINED)

**4470**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

### emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30 tablets

11104K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2016.85	38.80	Odefsey [GI]

### ▪ EMTRICITABINE + TENOFOVIR ALAFENAMIDE

#### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

#### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30**

11099E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1500.85	38.80	Descovy [GI]

**emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30**

11113X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1500.85	38.80	Descovy [GI]

**■ LAMIVUDINE + ZIDOVUDINE****Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**lamivudine 150 mg + zidovudine 300 mg tablet, 60**

10284G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*580.57	38.80	<sup>a</sup> Combivir [VI]	<sup>a</sup> Lamivudine 150 mg + Zidovudine 300 mg Alphapharm [AF]

**■ LOPINAVIR + RITONAVIR****Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**lopinavir 100 mg + ritonavir 25 mg tablet, 60**

10285H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*361.21	38.80	Kaletra [VE]

**lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL**

10327M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	5	..	*1329.55	38.80	Kaletra [VE]

**lopinavir 200 mg + ritonavir 50 mg tablet, 120**

10272P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1408.93	38.80	Kaletra [VE]

**■ TENOFOVIR + EMTRICITABINE**

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****6985**

HIV infection

Treatment Phase: Initial

## ANTIINFECTIVES FOR SYSTEMIC USE

### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Authority required (STREAMLINED)

**6986**

HIV infection

Treatment Phase: Continuing

### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### **tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

10347N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1268.25	38.80	<sup>a</sup> Truvada [GI]

### **tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30**

11146P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1268.25	38.80	<sup>a</sup> Tenofovir EMT GH [GQ]

### **tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30**

11149T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1268.25	38.80	<sup>a</sup> Tenofovir Disoproxil Emtricitabine Mylan 300/200 [AF]

### ■ **TENOFOVIR + EMTRICITABINE + EFAVIRENZ**

#### Authority required (STREAMLINED)

**4522**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive.

#### Authority required (STREAMLINED)

**4470**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

### **tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30**

10297Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1784.25	38.80	Atripla [GI]

### ■ **TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT**

#### Authority required (STREAMLINED)

**4522**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive.

#### Authority required (STREAMLINED)

**4470**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

### **tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30**

10307L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1784.25	38.80	Stribild [GI]

### ■ **TENOFOVIR + EMTRICITABINE + RILPIVIRINE**

#### Authority required (STREAMLINED)

**4522**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

**4470**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + rilpivirine 25 mg tablet, 30**

10314W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1784.25	38.80	Eviplera [GI]

▪ **TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT**

**Authority required (STREAMLINED)**

**4522**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

**4470**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30**

11114Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2016.85	38.80	Genvoya [GI]

HSD  
(Community)

*Other antivirals*

▪ **DOLUTEGRAVIR**

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**dolutegravir 50 mg tablet, 30**

10283F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1378.25	38.80	Tivicay [VI]

▪ **ENFUVIRTIDE**

**Authority required (STREAMLINED)**

**5014**

HIV infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

## ANTIINFECTIVES FOR SYSTEMIC USE

### enfuvirtide 90 mg injection [60 vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack

10365M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*4251.85	38.80	Fuzeon [RO]

#### ■ MARAVIROC

##### Authority required (STREAMLINED)

**5008**

HIV infection

##### Clinical criteria:

- Patient must be infected with CCR5-tropic HIV-1, **AND**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

### maraviroc 150 mg tablet, 60

10318C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1790.79	38.80	Celsentri [VI]

### maraviroc 300 mg tablet, 60

10355B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1790.79	38.80	Celsentri [VI]

#### ■ RALTEGRAVIR

##### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

##### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

##### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

##### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### raltegravir 400 mg tablet, 60

10286J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1311.69	38.80	Isentress [MK]

#### ■ RALTEGRAVIR

##### Authority required (STREAMLINED)

**4275**

HIV infection

Treatment Phase: Initial

##### Clinical criteria:

- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**
- Patient must have a CD4 count of less than 500 per cubic millimetre; OR
- Patient must have symptomatic HIV disease.

##### Population criteria:

- Patient must be aged 2 years or older.

##### Authority required (STREAMLINED)

**4274**

HIV infection

Treatment Phase: Continuing

##### Clinical criteria:

- The treatment must be in combination with other antiretroviral agents, **AND**

- Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**
- Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

- Patient must be aged 2 years or older.

**raltegravir 100 mg chewable tablet, 60**

10326L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*1970.95	38.80	Isentress [MK]

**raltegravir 25 mg chewable tablet, 60**

10299C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*507.37	38.80	Isentress [MK]

■ **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

■ **IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**

*Interferons*

■ **INTERFERON ALFA-2A**

Authority required (STREAMLINED)

**4993**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority required (STREAMLINED)

**5036**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
  - Patient must have detectable HBV DNA.
- Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

10317B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	30	5	..	*890.35	38.80	Roferon-A [RO]

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

10369R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	30	5	..	*2594.35	38.80	Roferon-A [RO]

■ **INTERFERON ALFA-2B**

Authority required (STREAMLINED)

**4993**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority required (STREAMLINED)

**5036**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

### interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL

10292Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1179.17	38.80	Intron A Redipen [MK]

### interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL

10316Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*595.81	38.80	Intron A Redipen [MK]

### interferon alfa-2b 18 million units/3 mL injection, 3 mL vial

10340F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15	5	..	*2594.20	38.80	Intron A [MK]

### interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials

10370T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*1462.18	38.80	Intron A [MK]

### interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial

10339E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15	5	..	*3584.80	38.80	Intron A [MK]

### interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL

10291P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*360.33	38.80	Intron A Redipen [MK]

## ■ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

#### **Authority required (STREAMLINED)**

##### **5010**

Chronic hepatitis B infection

#### **Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must not have previously received peginterferon alfa therapy for the treatment of hepatitis B, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; **OR**
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### **Authority required (STREAMLINED)**

##### **5067**

Chronic hepatitis B infection

#### **Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be limited to 1 course of treatment for a maximum duration of 48 weeks.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

### peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

10278Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2612.59	38.80	Pegasys [RO]

### peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

10280C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2262.37	38.80	Pegasys [RO]

■ **NERVOUS SYSTEM**

■ **PSYCHOLEPTICS**

**ANTIPSYCHOTICS**

*Diazepines, oxazepines, thiazepines and oxepines*

■ **CLOZAPINE**

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

**Authority required (STREAMLINED)**

**4998**

Schizophrenia

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

**clozapine 200 mg tablet, 100**

10288L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*511.31	38.80	Clopine 200 [PF]

**clozapine 100 mg tablet, 100**

10358E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*259.23	38.80	<sup>a</sup> Clopine 100 [PF]	<sup>a</sup> Clozaril 100 [NV]

**clozapine 25 mg tablet, 100**

10289M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*75.79	38.80	<sup>a</sup> Clopine 25 [PF]	<sup>a</sup> Clozaril 25 [NV]

**clozapine 50 mg tablet, 100**

10302F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*141.61	38.80	Clopine 50 [PF]

**clozapine 50 mg/mL oral liquid, 100 mL**

10341G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	147.55	38.80	Clopine Suspension [PF]

HSD  
(Community)

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# Botulinum Toxin Program

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MUSCULO-SKELETAL SYSTEM.....	1261
MUSCLE RELAXANTS .....	1261
MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS .....	1261

## ■ MUSCULO-SKELETAL SYSTEM

### ■ MUSCLE RELAXANTS

#### MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

*Other muscle relaxants, peripherally acting agents*

#### ■ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5221**

Blepharospasm or hemifacial spasm

**Clinical criteria:**

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**Population criteria:**

- Patient must be aged 12 years or older.

#### botulinum toxin type A 100 units injection, 1 vial

10997T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1626.07	38.80	Botox [AG]

#### ■ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5406**

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

#### botulinum toxin type A 100 units injection, 1 vial

11023E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1626.07	38.80	Botox [AG]

#### ■ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**5409**

Urinary incontinence

**Clinical criteria:**

- The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, **AND**
- The condition must be inadequately controlled by anti-cholinergic therapy, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, **AND**
- Patient must have multiple sclerosis; OR
- Patient must have a spinal cord injury; OR
- Patient must be aged 18 years or older and have spina bifida.

**Treatment criteria:**

- Must be treated by a urologist; OR
- Must be treated by a urogynaecologist.

**botulinum toxin type A 100 units injection, 1 vial**

10993N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1626.07	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5359**

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**Authority required (STREAMLINED)**

**5407**

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant, **AND**
- Patient must have commenced PBS-subsidised treatment with Botulinum Toxin Type A Purified Neurotoxin Complex as a paediatric patient.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**botulinum toxin type A 100 units injection, 1 vial**

10998W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1626.07	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**5262**

Chronic migraine

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin.

**Population criteria:**

- Patient must be aged 18 years or older.

Prophylactic migraine medications are propranolol, amitriptylin, methsergide, pizotifen, cyproheptadine or topiramate.

Botulinum

**botulinum toxin type A 100 units injection, 1 vial**

11000Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1626.07	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

Authority required (STREAMLINED)

**6953**

Urinary incontinence

**Treatment criteria:**

- Must be treated by a urologist; OR
- Must be treated by a gynaecologist.

**Clinical criteria:**

- The condition must be due to idiopathic overactive bladder, **AND**
- The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**botulinum toxin type A 100 units injection, 1 vial**

11004E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1626.07	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

Authority required (STREAMLINED)

**5408**

Severe primary axillary hyperhidrosis

**Clinical criteria:**

- Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; OR
- Patient must be intolerant to topical aluminium chloride hexahydrate treatment.

**Population criteria:**

- Patient must be aged 12 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a neurologist; OR
- Must be treated by a paediatrician.

Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.

**botulinum toxin type A 100 units injection, 1 vial**

11016T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1626.07	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

**5178**

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

- Patient must have cerebral palsy.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR

- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**Authority required (STREAMLINED)**

**5261**

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

- Patient must have cerebral palsy, **AND**
- Patient must have commenced PBS-subsidised treatment with Botulinum Type A Neurotoxin Complex as a paediatric patient.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**Note** Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

**Authority required (STREAMLINED)**

**5220**

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

**botulinum toxin type A 100 units injection, 1 vial**

10999X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1626.07	38.80	Botox [AG]

**■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5220**

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

10988H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1272.29	38.80	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

10982B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1420.91	38.80	Dysport [IS]

■ **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

**5405**

Blepharospasm or hemifacial spasm

**Clinical criteria:**

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11022D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1272.29	38.80	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

10987G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1420.91	38.80	Dysport [IS]

■ **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

**5406**

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11015R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1272.29	38.80	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

11007H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1420.91	38.80	Dysport [IS]

▪ **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5359**

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**Authority required (STREAMLINED)**

**5332**

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must be an ambulant cerebral palsy patient, **AND**
- Patient must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11006G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1272.29	38.80	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

10981Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1420.91	38.80	Dysport [IS]

▪ **INCOBOTULINUMTOXINA**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5220**

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.  
Standard management includes physiotherapy and/or oral spasticity agents.

**incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial**

10983C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1547.15	38.80	Xeomin [EZ]

▪ **INCOBOTULINUMTOXINA**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5360**

Blepharospasm

**Clinical criteria:**

- Patient must have blepharospasm.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial**

10994P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1547.15	38.80	Xeomin [EZ]

▪ **INCOBOTULINUMTOXINA**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5222**

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**Population criteria:**

- Patient must be aged 18 years or older.

**incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial**

11005F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1547.15	38.80	Xeomin [EZ]

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# Growth Hormone Program

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SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	1269
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES .....	1269
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES .....	1269

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

#### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

##### *Somatropin and somatropin agonists*

#### SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

#### **Population criteria:**

- Patient must be aged 3 years or older.

#### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
- (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95<sup>th</sup> percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
- (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
- (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

10514J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Omnitrope Surepal 10 [SZ]

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

6311E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Omnitrope [SZ]

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

10518N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Omnitrope Surepal 5 [SZ]

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

10446T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Omnitrope Surepal 15 [SZ]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
 (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

## **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

## **Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven

biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven

biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95<sup>th</sup> percentile for age on the Turner syndrome growth curve for girls, **AND**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

### **Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; **OR**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; **OR**
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### somatropin 12 units (4 mg) injection [1 vial] (& inert substance diluent [1 vial], 1 pack

6266T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	180.12	38.80	Zomacton [FP]

### somatropin 30 units (10 mg) injection [1 vial] (& inert substance diluent [1 mL syringe], 1 pack

6310D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Zomacton [FP]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR

- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Confirmation that the patient has precocious puberty; **AND**
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

- (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
 (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion;  
 AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95<sup>th</sup> percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
 (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge**

3388H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	872.01	38.80	Saizen [SG]

**somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge**

5822K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	266.61	38.80	Saizen [SG]

**somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge**

5824M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Saizen [SG]

■ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**

- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

#### Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation of the patient's maturational or constitutional delay status; **AND**
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

#### Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

**Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
  - Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
  - Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.
- The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; **OR**
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; **OR**
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
- (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more. The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95<sup>th</sup> percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND  
 6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
 (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> ; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

5819G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Norditropin FlexPro [NO]

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

6296J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Norditropin SimpleXx [NO]

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

5818F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Norditropin FlexPro [NO]

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

6295H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Norditropin SimpleXx [NO]

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

5820H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Norditropin FlexPro [NO]

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

6297K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Norditropin SimpleXx [NO]

**somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge**

9604L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	NutropinAq [IS]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
 (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

**Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,

clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,

clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95<sup>th</sup> percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

#### **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

#### **Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### **Population criteria:**

- Patient must be prepubertal.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6345Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1044.99	38.80	Humatrope [LY]

### somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6169Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	266.61	38.80	Humatrope [LY]

### somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6170R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Humatrope [LY]

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

### **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Confirmation that the patient has precocious puberty; **AND**
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND  
 9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95<sup>th</sup> percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
 (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

**AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a chronological age of 18 years or greater.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND
4. The date that skeletal maturity was achieved (if applicable); AND
5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR  
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist
6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; AND

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with 1 repeat allowed)

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6316K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	430.93	38.80	Genotropin MiniQuick [PF]

### somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6318M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	552.02	38.80	Genotropin MiniQuick [PF]

### somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6319N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	612.55	38.80	Genotropin MiniQuick [PF]

### somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6317L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	491.48	38.80	Genotropin MiniQuick [PF]

### SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

9585L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Genotropin GoQuick [PF]

### SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

9586M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Genotropin GoQuick [PF]

### somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack

10902T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	128.23	38.80	Genotropin MiniQuick [PF]

### somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6314H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	309.85	38.80	Genotropin MiniQuick [PF]

### somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack

6312F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Genotropin [PF]

### somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6315J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	370.39	38.80	Genotropin MiniQuick [PF]

### somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6313G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	249.31	38.80	Genotropin MiniQuick [PF]

### somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

9628R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	188.78	38.80	Genotropin MiniQuick [PF]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

#### **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

#### **Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND  
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,

clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**

- (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
 (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
 (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

**Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
 (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### somatropin 12 units (4 mg) injection [1 vial] (& inert substance diluent [1 vial], 1 pack

10452D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	180.12	38.80	Zomacton [FP]

### somatropin 30 units (10 mg) injection [1 vial] (& inert substance diluent [1 mL syringe], 1 pack

10440L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Zomacton [FP]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

#### **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; **OR**  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; **AND**
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

## somatropin 12 units (4 mg) injection [1 vial] (& inert substance diluent [1 vial], 1 pack

10447W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	180.12	38.80	Zomacton [FP]

## somatropin 30 units (10 mg) injection [1 vial] (& inert substance diluent [1 mL syringe], 1 pack

10455G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Zomacton [FP]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR



- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

### Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR



- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR
- Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup> ; **AND**
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**

The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10441M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Omnitrope [SZ]

### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10506Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Omnitrope Surepal 10 [SZ]

### somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10507B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Omnitrope Surepal 5 [SZ]

### somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10490D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Omnitrope Surepal 15 [SZ]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**



- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,

clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup> ; **AND**
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10439K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Norditropin SimpleXx [NO]

### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10451C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Norditropin FlexPro [NO]

### somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10432C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Norditropin FlexPro [NO]

### somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10469B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Norditropin SimpleXx [NO]

### somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10449Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Norditropin FlexPro [NO]

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

10468Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Norditropin SimpleXx [NO]

**somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge**

10478L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	NutropinAq [IS]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**

- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**

### **AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup> ; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge**

10497L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	872.01	38.80	Saizen [SG]

**somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge**

10462P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	266.61	38.80	Saizen [SG]

**somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge**

10483R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Saizen [SG]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

**Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR



- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

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- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be prepubertal.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; **OR**  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; **AND**
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic

dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be prepubertal.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup> ; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10476J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1044.99	38.80	Humatrope [LY]

### somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10482Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	266.61	38.80	Humatrope [LY]

### somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10487Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Humatrope [LY]

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Population criteria:**

- Patient must be aged 3 years or older.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Population criteria:**

- Patient must be aged 3 years or older.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> ; **AND**
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10481P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Omnitrope [SZ]

### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10519P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Omnitrope Surepal 10 [SZ]

### somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10512G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Omnitrope Surepal 5 [SZ]

### somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10485W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Omnitrope Surepal 15 [SZ]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with Turner syndrome  
Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders  
Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

#### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

#### Population criteria:

- Patient must be prepubertal.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

#### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; **AND**
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; **OR**  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Recent growth data (height and weight, not older than three months); **AND**
9. A bone age result performed within the last 12 months; **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be prepubertal.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10502R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1044.99	38.80	Humatrope [LY]

### somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10429X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	266.61	38.80	Humatrope [LY]

### somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10461N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Humatrope [LY]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

#### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

#### Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

#### Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**

- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; **AND**
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
 (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); **OR**  
 (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; **OR**  
 (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Commencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each commencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for commencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Commencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotrin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; **OR**  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Recent growth data (height and weight, not older than three months); **AND**
9. A bone age result performed within the last 12 months; **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
- Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
  - If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
  - Recent growth data (height and weight, not older than three months); AND
  - A bone age result performed within the last 12 months; AND
  - The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10448X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Norditropin SimpleXx [NO]

### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10496K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	Norditropin FlexPro [NO]

### somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10437H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Norditropin SimpleXx [NO]

### somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10467X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Norditropin FlexPro [NO]

### somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10470C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Norditropin SimpleXx [NO]

### somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10489C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.80	38.80	Norditropin FlexPro [NO]

### somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge

10438J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.58	38.80	NutropinAq [IS]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

- (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
  5. Recent growth data (height and weight, not older than three months); AND
  6. A bone age result performed within the last 12 months; AND
  7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

#### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic

dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

- (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
 (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
 (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; **OR**  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Recent growth data (height and weight, not older than three months); **AND**
9. A bone age result performed within the last 12 months; **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
- (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6

- months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
  5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
  6. Recent growth data (height and weight, not older than three months); AND
  7. A bone age result performed within the last 12 months; AND
  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge**

10442N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	872.01	38.80	Saizen [SG]

**somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge**

10458K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	266.61	38.80	Saizen [SG]

**somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge**

10495J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Saizen [SG]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

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- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader Willi syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Population criteria:**

- Patient must not have a chronological age of equal to or greater than 18 years.

**Clinical criteria:**

- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height, weight, and waist circumference, not older than three months); AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND

5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of

growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
 (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
 (c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

### **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic

dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Recent growth data (height and weight, not older than three months); **AND**
9. A bone age result performed within the last 12 months; **AND**

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### **Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems,

**AND**

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

**AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 18 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR  
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; **AND**
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. The date that skeletal maturity was achieved (if applicable); **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10434E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	430.93	38.80	Genotropin MiniQuick [PF]

**somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10501Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	552.02	38.80	Genotropin MiniQuick [PF]

**somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10472E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	612.55	38.80	Genotropin MiniQuick [PF]

**somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10498M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	491.48	38.80	Genotropin MiniQuick [PF]

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1**

10435F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Genotropin GoQuick [PF]

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1**

10426R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Genotropin GoQuick [PF]

**somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack**

10908D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	128.23	38.80	Genotropin MiniQuick [PF]

**somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10430Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	309.85	38.80	Genotropin MiniQuick [PF]

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack**

10444Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Genotropin [PF]

**somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10457J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	370.39	38.80	Genotropin MiniQuick [PF]

**somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10463Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	249.31	38.80	Genotropin MiniQuick [PF]

**somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10477K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	188.78	38.80	Genotropin MiniQuick [PF]

**▪ SOMATROPIN**

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

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- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category, **AND**
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved height percentile for age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

- Patient must have maintained or improved waist circumference while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must not have been on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved waist circumference while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/week for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Population criteria:**

- Patient must not have a chronological age of equal to or greater than 18 years.

**Clinical criteria:**

- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height, weight and waist circumference) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND
5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR  
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR  
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**  
 (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25<sup>th</sup> percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25<sup>th</sup> percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR  
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup> ; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems,

**AND**

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

**AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 18 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR  
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; **AND**
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. The date that skeletal maturity was achieved (if applicable); **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

 Reply Paid 9826  
 HOBART TAS 7001

**somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10488B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	430.93	38.80	Genotropin MiniQuick [PF]

**somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10500P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	552.02	38.80	Genotropin MiniQuick [PF]

**somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10428W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	612.55	38.80	Genotropin MiniQuick [PF]

**somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10454F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	491.48	38.80	Genotropin MiniQuick [PF]

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1**

10443P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.37	38.80	Genotropin GoQuick [PF]

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1**

10431B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Genotropin GoQuick [PF]

**somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack**

10891F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	128.23	38.80	Genotropin MiniQuick [PF]

**somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10480N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	309.85	38.80	Genotropin MiniQuick [PF]

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack**

10499N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.07	38.80	Genotropin [PF]

**somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10453E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	370.39	38.80	Genotropin MiniQuick [PF]

**somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10479M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	249.31	38.80	Genotropin MiniQuick [PF]

**somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

10456H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	188.78	38.80	Genotropin MiniQuick [PF]

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# IVF Treatment Program

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GENITO URINARY SYSTEM AND SEX HORMONES .....	1544
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM .....	1544
PROGESTOGENS.....	1544
GONADOTROPINS AND OTHER OVULATION STIMULANTS .....	1544
<hr/>	
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	1547
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES .....	1547
HYPOTHALAMIC HORMONES.....	1547
<hr/>	
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	1547
ENDOCRINE THERAPY .....	1547
HORMONES AND RELATED AGENTS .....	1547

▪ GENITO URINARY SYSTEM AND SEX HORMONES

▪ SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

PROGESTOGENS

*Pregnen (4) derivatives*

▪ PROGESTERONE

**Authority required (STREAMLINED)**

**4997**

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

**progesterone 100 mg pessary, 15**

9608Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*156.55	38.80	Oripro [ON]

**progesterone 200 mg capsule, 42**

10930G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	86.68	38.80	Utrogestan [HB]

**progesterone 200 mg pessary, 15**

9609R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*171.94	38.80	Oripro [ON]

**progesterone 100 mg pessary, 21**

10116K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*104.99	38.80	Endometrin [FP]

▪ PROGESTERONE

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**5045**

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

**progesterone 8% vaginal gel, 15 applications**

6366C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*300.59	38.80	Crinone 8% [SG]

GONADOTROPINS AND OTHER OVULATION STIMULANTS

*Gonadotropins*

▪ CHORIOGONADOTROPIN ALFA

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**5019**

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 dose**

6182J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	63.21	38.80	Ovidrel [SG]

IVF

▪ **CORIFOLLITROPIN ALFA**

**Authority required (STREAMLINED)**

**5009**

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for controlled ovarian stimulation, **AND**
- Patient must have an antral follicle count of 20 or less, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule, **AND**
- Patient must be undergoing a gonadotrophin releasing antagonist cycle.

**corifollitropin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**

5816D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	412.37	38.80	Elonva [MK]

**corifollitropin alfa 150 microgram/0.5 mL injection, 0.5 mL syringe**

5817E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	672.57	38.80	Elonva [MK]

▪ **FOLLITROPIN ALFA**

**Authority required (STREAMLINED)**

**5027**

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge**

6433N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1684.55	38.80	Gonal-f Pen [SG]

**follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices**

10866X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1684.54	38.80	Bemfola [FX]

**follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices**

10872F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1275.19	38.80	Bemfola [FX]

**follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices**

10861P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*432.88	38.80	Bemfola [FX]

**follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge**

6431L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*234.21	38.80	Gonal-f Pen [SG]

**follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge**

6432M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*347.73	38.80	Gonal-f Pen [SG]

**follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices**

10873G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*858.61	38.80	Bemfola [FX]

**follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices**

10867Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*2503.24	38.80	Bemfola [FX]

▪ **FOLLITROPIN ALFA + LUTROPIN ALFA**

**Authority required (STREAMLINED)**

**5250**

Stimulation of follicular development

**Clinical criteria:**

- Patient must have severe LH deficiency, **AND**

IVF

## GENITO URINARY SYSTEM AND SEX HORMONES

- Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment, **AND**
- Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### **follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&) inert substance diluent [1 vial], 1 pack**

10491E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	14	..	..	*2186.95	38.80	Pergoveris [SG]

### ▪ **FOLLITROPIN BETA**

#### **Authority required (STREAMLINED)**

**5027**

Assisted Reproductive Technology

#### **Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### **follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge**

6464F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*2114.10	38.80	Puregon 900 IU/1.08 mL [MK]

### **follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge**

6335K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*303.55	38.80	Puregon 300 IU/0.36 mL [MK]

### **follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge**

6336L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1159.47	38.80	Puregon 600 IU/0.72 mL [MK]

### ▪ **HUMAN CHORIONIC GONADOTROPHIN**

#### **Authority required (STREAMLINED)**

**6991**

Assisted Reproductive Technology

#### **Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### **human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack**

11156E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.33	28.54	Pregnyl [MK]

### **human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

11154C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	41.89	38.80	Pregnyl [MK]

### ▪ **HUMAN MENOPAUSAL GONADOTROPHIN**

#### **Authority required (STREAMLINED)**

**5027**

Assisted Reproductive Technology

#### **Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### **human menopausal gonadotrophin 1200 units injection [1 vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack**

2038G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2171.87	38.80	Menopur 1200 [FP]

### **human menopausal gonadotrophin 600 units injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

2036E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*835.78	38.80	Menopur 600 [FP]

### ▪ **LUTROPIN ALFA**

#### **Authority required (STREAMLINED)**

**5251**

Stimulation of follicular development

#### **Clinical criteria:**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must have severe LH deficiency, **AND**
- Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### lutropin alfa 75 units injection [1 vial] (& inert substance diluent [1 mL vial], 1 pack

10465T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	14	..	..	*1422.69	38.80	Luveris [SG]

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

#### HYPOTHALAMIC HORMONES

##### Gonadotropin-releasing hormones

#### NAFARELIN

##### Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

##### Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### nafarelin 200 microgram/actuation nasal spray, 60 actuations

5815C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*227.63	38.80	Synarel [PF]

##### Anti-gonadotropin-releasing hormones

#### CETRORELIX

##### Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

##### Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### cetorelix 250 microgram injection [1 vial] (& inert substance diluent [1 mL syringe], 1 pack

9599F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*462.45	38.80	Cetrotide [SG]

#### GANIRELIX

##### Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

##### Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### ganirelix 250 microgram/0.5 mL injection, 0.5 mL syringe

9583J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*462.45	38.80	Orgalutran [MK]

### ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes

9584K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*462.47	38.80	Orgalutran [MK]

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### ENDOCRINE THERAPY

#### HORMONES AND RELATED AGENTS

##### Gonadotropin releasing hormone analogues

▪ **TRIPTORELIN**

**Authority required (STREAMLINED)**

**5046**

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**triptorelin acetate 100 microgram/mL injection, 7 x 1 mL syringes**

10907C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*216.59	38.80	Decapeptyl [FP]

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# Opiate Dependence Treatment Program

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NERVOUS SYSTEM.....	1550
OTHER NERVOUS SYSTEM DRUGS.....	1550
DRUGS USED IN ADDICTIVE DISORDERS.....	1550

■ **NERVOUS SYSTEM**

■ **OTHER NERVOUS SYSTEM DRUGS**

**DRUGS USED IN ADDICTIVE DISORDERS**

*Drugs used in opioid dependence*

■ **BUPRENORPHINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Opiate dependence

Treatment Phase: Maintenance and detoxification (withdrawal)

**Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment.

**buprenorphine 2 mg sublingual tablet, 7**

6308B	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	9.98	Subutex [IR]

**buprenorphine 400 microgram sublingual tablet, 7**

6307Y	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	5.85	Subutex [IR]

**buprenorphine 8 mg tablet, 7**

6309C	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	28.60	Subutex [IR]

■ **BUPRENORPHINE + NALOXONE**

**Note** Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Opiate dependence

**Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment.

**buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28**

9749D	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	46.20	Suboxone Film 2/0.5 [IR]

**buprenorphine 8 mg + naloxone 2 mg sublingual film, 28**

9750E	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	132.44	Suboxone Film 8/2 [IR]

■ **METHADONE**

**Caution** The risk of drug dependence is high.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.


**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.


**Restricted benefit**

Opiate dependence

**methadone hydrochloride 5 mg/mL oral liquid, 1 L**

6172W	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	33.20	<sup>a</sup> Aspen Methadone Syrup [QA]	<sup>a</sup> Biodone Forte [MW]

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

6171T	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	7.91	<sup>a</sup> Aspen Methadone Syrup [QA]	<sup>a</sup> Biodone Forte [MW]

# Repatriation Pharmaceutical Benefits Scheme

## BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

### Gold card

This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.

### White card

A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:

- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.

### Orange card

Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:

- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.



For more information go to the Department of Veterans' Affairs website:  
<http://www.dva.gov.au>

# RPBS Explanatory Notes

## Introduction

### *The Australian Repatriation System*

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

### RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient's full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

### Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
  - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the *National Health Act 1953*; and
  - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department's national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
  - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
  - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
  - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

### Palliative Care Drugs

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam
  - cyclizine
  - dexamethasone

- disodium pamidronate
- fentanyl
- glycopyrrolate
- hyoscine butylbromide
- hyoscine hydrobromide
- ketamine
- midazolam
- octreotide
- For further information telephone VAPAC on 1800 552 580.

### **Dental Prescribing**

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

### **Prescribing by optometrists**

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

## **Provisions governing pricing and payment for RPBS benefits**

### **Introduction**

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

### **Pricing of Schedule Items**

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

### **Pricing of Non-Schedule Ready Prepared Items**

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than \$100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

### **Pricing of Non-Schedule Extemporaneously Prepared Items**

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

### **Miscellaneous Pricing Rules**

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.

- 
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
  - For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

## **General**

### ***Packaging Material, Postage or Freight***

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacist's itemised receipt.

### ***Payment for Items Supplied at Short Intervals***

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

### ***Receipts for Patient Charges***

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patient's name and address. The patient may apply for reimbursement from the Department.

### ***Special Patient Contributions***

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

### ***Therapeutic Group Premiums — Authority Processing***

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

## **Contact the Department of Veterans' Affairs**

### **Authority Prescription Applications**

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998

VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

**For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is: 1800 552 580**

**Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.**

## WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

### DRESSINGS

#### Pink Epithelialising Wound

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering	<ul style="list-style-type: none"> <li>○ Film;</li> <li>○ Film Island</li> </ul>	<ul style="list-style-type: none"> <li>○ Gauze—Paraffin;</li> <li>○ Non-adherent</li> </ul>
(B) Absorbing	<ul style="list-style-type: none"> <li>○ Foam (Light Exudate);</li> <li>○ Hydroactive (Superficial Wound—Light Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>○ Hydrocolloid (Superficial Wound—Light Exudate)</li> </ul>

#### Red Granulating Wound

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"> <li>○ Foam (Light Exudate);</li> <li>○ Hydroactive (Superficial Wound—Light Exudate);</li> <li>○ Hydrocolloid (Superficial Wound—Light Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>○ Hydrocolloid (Cavity Wound)</li> </ul>
(B) Moisture donating	<ul style="list-style-type: none"> <li>○ Hydrogel—Amorphous;</li> <li>○ Hydrogel—Sheet</li> </ul>	<ul style="list-style-type: none"> <li>○ Hydrogel—Amorphous</li> </ul>
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"> <li>○ Alginate (Superficial Wound);</li> <li>○ Foam—Heavy Exudate;</li> <li>○ Hydroactive (Superficial Wound—Moderate Exudate);</li> <li>○ Hydrocolloid (Superficial Wound—Moderate/High Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>○ Alginate (Cavity Wound);</li> <li>○ Foam—Moderate Exudate (see “cavity conforming” product);</li> <li>○ Hydroactive (Cavity Wound);</li> <li>○ Hydrocolloid (Cavity Wound)</li> </ul>
(B) Moisture donating	NOT APPROPRIATE	

#### Yellow Sloughy Wound

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"> <li>○ Cadexomer Iodine;</li> <li>○ Foam—Light Exudate;</li> <li>○ Foam with Charcoal;</li> <li>○ Hydroactive (Superficial Wound—Moderate Exudate);</li> <li>○ Hydrocolloid (Superficial Wound—Moderate Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>○ Cadexomer Iodine;</li> <li>○ Hydrocolloid (Cavity Wound)</li> </ul>
(B) Moisture Donating	<ul style="list-style-type: none"> <li>○ Hydrogel—Amorphous;</li> <li>○ Hydrogel—Sheet</li> </ul>	<ul style="list-style-type: none"> <li>○ Hydrogel—Amorphous</li> </ul>
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"> <li>○ Alginate (Superficial Wound);</li> <li>○ Cadexomer Iodine;</li> <li>○ Foam—Heavy Exudate;</li> <li>○ Hydroactive (Superficial Wound—Moderate/High Exudate);</li> <li>○ Hydrocolloid (Superficial Wound—Moderate/High Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>○ Alginate (Cavity Wound);</li> <li>○ Cadexomer Iodine;</li> <li>○ Hydrocolloid (Cavity Wound)</li> </ul>
(B) Moisture donating	NOT APPROPRIATE	

### Black Necrotic Wound

Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

DRY / LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"><li>○ Hydroactive (Superficial Wound—Light Exudate);</li><li>○ Hydrocolloid (Superficial Wound—Light/Moderate Exudate)</li></ul>	<ul style="list-style-type: none"><li>○ Hydrocolloid (Cavity Wound)</li></ul>
(B) Moisture donating	<ul style="list-style-type: none"><li>○ Hydrogel—Amorphous;</li><li>○ Hydrogel—Sheet</li></ul>	<ul style="list-style-type: none"><li>○ Hydrogel—Amorphous;</li><li>○ Hydrogel—Sheet</li></ul>

### Infected Wounds

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

### Malodorous Wounds

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria in slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

### Minor Skin Trauma

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

## Ordering Products

### Ordering Coloplast Products

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### Ordering Hartmann Products

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### Ordering Molnlycke Healthcare Products

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email [customerservice@independenceaustralia.com](mailto:customerservice@independenceaustralia.com). Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

### Ordering Smith & Nephew Products

Smith & Nephew products are distributed via the three major wholesalers, API, SIGMA & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

ALIMENTARY TRACT AND METABOLISM.....	1561
STOMATOLOGICAL PREPARATIONS .....	1561
STOMATOLOGICAL PREPARATIONS.....	1561
DRUGS FOR ACID RELATED DISORDERS.....	1561
ANTACIDS .....	1561
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS.....	1561
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS .....	1561
BELLADONNA AND DERIVATIVES, PLAIN .....	1561
DRUGS FOR CONSTIPATION .....	1562
DRUGS FOR CONSTIPATION.....	1562
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS.....	1563
ELECTROLYTES WITH CARBOHYDRATES .....	1563
ANTIPROPULSIVES.....	1563
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS .....	1563
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS .....	1563
VITAMINS.....	1564
VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12.....	1564
VITAMIN B-COMPLEX, INCL. COMBINATIONS .....	1564
MINERAL SUPPLEMENTS .....	1564
CALCIUM.....	1564
OTHER MINERAL SUPPLEMENTS.....	1565
<hr/>	
BLOOD AND BLOOD FORMING ORGANS .....	1565
ANTITHROMBOTIC AGENTS.....	1565
ANTITHROMBOTIC AGENTS .....	1565
ANTIANEMIC PREPARATIONS .....	1566
IRON PREPARATIONS.....	1566
VITAMIN B12 AND FOLIC ACID .....	1566
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS .....	1567
IRRIGATING SOLUTIONS .....	1567
<hr/>	
CARDIOVASCULAR SYSTEM.....	1567
VASOPROTECTIVES .....	1567
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE.....	1567
<hr/>	
DERMATOLOGICALS .....	1567
ANTIFUNGALS FOR DERMATOLOGICAL USE .....	1567
ANTIFUNGALS FOR TOPICAL USE.....	1567
ANTIFUNGALS FOR SYSTEMIC USE.....	1568
EMOLLIENTS AND PROTECTIVES.....	1569
EMOLLIENTS AND PROTECTIVES .....	1569
PROTECTIVES AGAINST UV-RADIATION .....	1569
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. ....	1570
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.....	1570
ANTIPSORIATICS.....	1570
ANTIPSORIATICS FOR TOPICAL USE.....	1570
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE.....	1570

ANTIBIOTICS FOR TOPICAL USE .....	1570
CHEMOTHERAPEUTICS FOR TOPICAL USE.....	1570
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS .....	1571
CORTICOSTEROIDS, PLAIN.....	1571
ANTISEPTICS AND DISINFECTANTS .....	1571
ANTISEPTICS AND DISINFECTANTS .....	1571
OTHER DERMATOLOGICAL PREPARATIONS .....	1572
OTHER DERMATOLOGICAL PREPARATIONS.....	1572
<hr/>	
GENITO URINARY SYSTEM AND SEX HORMONES .....	1573
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS .....	1573
ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS .....	1573
OTHER GYNECOLOGICALS.....	1574
OTHER GYNECOLOGICALS .....	1574
UROLOGICALS .....	1574
UROLOGICALS .....	1574
DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY .....	1576
<hr/>	
ANTIINFECTIVES FOR SYSTEMIC USE .....	1577
ANTIBACTERIALS FOR SYSTEMIC USE.....	1577
MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS.....	1577
<hr/>	
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	1577
ANTINEOPLASTIC AGENTS .....	1577
ANTIMETABOLITES .....	1577
IMMUNOSUPPRESSANTS.....	1577
IMMUNOSUPPRESSANTS .....	1577
<hr/>	
MUSCULO-SKELETAL SYSTEM.....	1578
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN .....	1578
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN .....	1578
DRUGS FOR TREATMENT OF BONE DISEASES .....	1578
DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION.....	1578
<hr/>	
NERVOUS SYSTEM.....	1580
ANALGESICS .....	1580
OPIOIDS .....	1580
OTHER ANALGESICS AND ANTIPYRETICS .....	1580
PSYCHOLEPTICS.....	1581
ANXIOLYTICS .....	1581
HYPNOTICS AND SEDATIVES .....	1582
OTHER NERVOUS SYSTEM DRUGS.....	1583
DRUGS USED IN ADDICTIVE DISORDERS .....	1583
<hr/>	
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS.....	1583
ANTHELMINTICS.....	1583
ANTINEMATODAL AGENTS.....	1583

RESPIRATORY SYSTEM.....	1583
NASAL PREPARATIONS.....	1583
DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE .....	1583
NASAL DECONGESTANTS FOR SYSTEMIC USE.....	1584
COUGH AND COLD PREPARATIONS.....	1584
EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS.....	1584
COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS.....	1585
ANTIHISTAMINES FOR SYSTEMIC USE .....	1585
ANTIHISTAMINES FOR SYSTEMIC USE.....	1585
<hr/>	
SENSORY ORGANS .....	1585
OPHTHALMOLOGICALS .....	1585
DECONGESTANTS AND ANTIALLERGICS.....	1585
OTOLOGICALS .....	1586
OTHER OTOLOGICALS.....	1586
<hr/>	
VARIOUS .....	1586
ALL OTHER THERAPEUTIC PRODUCTS .....	1586
ALL OTHER THERAPEUTIC PRODUCTS.....	1586
GENERAL NUTRIENTS .....	1586
OTHER NUTRIENTS .....	1586
ALL OTHER NON-THERAPEUTIC PRODUCTS .....	1587
ALL OTHER NON-THERAPEUTIC PRODUCTS .....	1587

## ALIMENTARY TRACT AND METABOLISM

### STOMATOLOGICAL PREPARATIONS

#### STOMATOLOGICAL PREPARATIONS

*Antifungives and antiseptics for local oral treatment*

#### CHLORHEXIDINE

**chlorhexidine gluconate 0.2% mouthwash, 300 mL**

4204G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.79	6.30	Savacol Mouth and Throat Rinse [OM]

**chlorhexidine gluconate 0.2% mouthwash, 250 mL**

4161B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.85	6.30	Plaqacide [OB]

#### NYSTATIN

**nystatin 100 000 units/mL oral liquid, 24 mL**

10854G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	17.57	6.30	<sup>a</sup> Pharmacy Action Nystatin Oral Drops [GQ]
			..	18.81	6.30	<sup>a</sup> Mycostatin Oral Drops [QA]

## DRUGS FOR ACID RELATED DISORDERS

### ANTACIDS

*Calcium compounds*

#### CALCIUM CARBONATE + GLYCINE

**Note** For patients with chronic renal failure.

**calcium carbonate 420 mg + glycine 180 mg chewable tablet, 100**

4055K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*25.67	6.30	Titralac [MM]

*Combinations and complexes of aluminium, calcium and magnesium compounds*

#### ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE

**ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1**

4118R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*25.19	6.30	Mylanta Double Strength [JT]

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

*Synthetic anticholinergics, esters with tertiary amino group*

#### MEBEVERINE

**mebeverine hydrochloride 135 mg tablet, 90**

4328T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	28.91	6.30	<sup>a</sup> Colese [AF]
			..	33.41	6.30	<sup>a</sup> Colofac [GO]

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

#### HYOSCINE BUTYLBROMIDE

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

4279F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	23.43	6.30	Buscopan [VZ]

## DRUGS FOR CONSTIPATION

### DRUGS FOR CONSTIPATION

*Softeners, emollients*

#### DOCUSATE

**docusate sodium 50 mg tablet, 100**

4200C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	17.95	6.30	Coloxyl 50 [FM]

*Contact laxatives*

#### BISACODYL

**bisacodyl 10 mg suppository, 12**

10580W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	4	..	*21.43	6.30	Petrus Bisacodyl Suppositories [PP]

**bisacodyl 10 mg suppository, 10**

10578R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*23.71	6.30	<sup>a</sup> Petrus Bisacodyl Suppositories [PP]
			..	*25.00	6.30	<sup>a</sup> Dulcolax [VZ]

#### DOCUSATE + SENNOSIDE B

**docusate sodium 50 mg + sennoside B 8 mg tablet, 100**

4028B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	18.04	6.30	Soflax [EA]

**docusate sodium 50 mg + sennoside B 8 mg tablet, 90**

10177P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	16.93	6.30	Pharmacy Action Laxative with Senna [GQ]

#### DOCUSATE + SENNOSIDES

**docusate sodium 50 mg + sennosides 11.27 mg tablet, 90**

4198Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	16.97	6.30	<sup>a</sup> Chemists' Own Laxative with Senna [RW]	<sup>a</sup> Colaxsen [QA]
			..	20.02	6.30	<sup>a</sup> Co-Senna [PP]	<sup>a</sup> Coloxyl with Senna [FM]

#### SENNOSIDE B

**sennoside B 7.5 mg tablet, 100**

4455L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	16.46	6.30	<sup>a</sup> Senna-Gen [PP]
			..	17.56	6.30	<sup>a</sup> Senokot [RC]

*Bulk-forming laxatives*

#### DRY PSYLLIUM HUSK

**dry psyllium husk 3.5 g powder for oral liquid, 30 sachets**

4285M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	20.85	6.30	Fybogel [RC]

#### PSYLLIUM HUSK POWDER

**PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (orange-flavoured, sugar-free) 283 g, 1**

4419N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	24.35	6.30	Metamucil Orange Smooth [PY]

**PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (non-flavoured) 336 g, 1**

4422R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	21.18	6.30	Fibre Health Natural Granular [PP]

..	24.35	6.30	Metamucil Natural Granular [PY]
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### ▪ RHAMNUS FRANGULA + STERCULIA

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

4558X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	27.57	6.30	Normacol Plus [NE]

#### Enemas

### ▪ SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM

**sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL**

4462W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.03	6.30	Micolette [AE]

#### Other drugs for constipation

### ▪ GLYCEROL

**glycerol 1.4 g suppository, 12**

10596Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*23.32	6.30	Petrus Pharmaceuticals Pty Ltd [PP]

**glycerol 2.8 g suppository, 12**

4246L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*23.80	6.30	Petrus Pharmaceuticals Pty Ltd [PP]

**glycerol 700 mg suppository, 12**

10586E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*22.96	6.30	Petrus Pharmaceuticals Pty Ltd [PP]

## ▪ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

### ELECTROLYTES WITH CARBOHYDRATES

#### Oral rehydration salt formulations

### ▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

**sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

10574M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.90	6.30	restore O.R.S. [EA]

### ANTIPROPULSIVES

#### Antipropulsives

### ▪ LOPERAMIDE

**loperamide hydrochloride 2 mg capsule, 12**

10592L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	12.58	6.30	Gastrex [CR]

**loperamide hydrochloride 2 mg capsule, 20**

11135C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	12.58	6.30	Pharmacy Action Diarrhoea Relief [GQ]

## ▪ ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS

### ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS

#### Peripherally acting antiobesity products

### ▪ ORLISTAT

**Note** The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

#### Authority required

Obesity

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR
- Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities;(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime.

The prescriber must provide the patient's initial body weight and BMI at the time of application.

**Authority required**

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their initial body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

**Authority required**

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their initial body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

**orlistat 120 mg capsule, 84**

4570M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	132.67	6.30	Xenical [RO]

■ **VITAMINS**

**VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12**

*Vitamin B1, plain*

■ **THIAMINE**

**thiamine hydrochloride 100 mg tablet, 100**

4043T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	14.98	6.30	Betavit [PP]

**VITAMIN B-COMPLEX, INCL. COMBINATIONS**

*Vitamin B-complex, plain*

■ **FERRIC PYROPHOSPHATE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + LYSINE**

**cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL + lysine hydrochloride 300 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + thiamine hydrochloride 10 mg/10 mL oral liquid, 200 mL**

4493L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	17.11	6.30	Accomin Adult Tonic [PF]

■ **MINERAL SUPPLEMENTS**

**CALCIUM**

*Calcium*

■ **CALCIUM**

**Restricted benefit**

Hyperphosphataemia

**Clinical criteria:**

- The condition must be associated with chronic renal failure.

**CALCIUM Tablet (chewable) 500 mg (as carbonate), 60**

4094L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	1	..	*29.67	6.30	Cal-500 [PP]

**CALCIUM Tablet 600 mg (as carbonate), 120**

4142B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*24.13	6.30	CAL-600 [PP]

▪ **CALCIUM**

Restricted benefit

Hypocalcaemia

Restricted benefit

Osteoporosis

Restricted benefit

Proven calcium malabsorption

**CALCIUM Tablet (chewable) 500 mg (as carbonate), 60**

4333C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*20.37	6.30	Cal-500 [PP]

**CALCIUM Tablet 600 mg (as carbonate), 120**

4082W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	17.61	6.30	CAL-600 [PP]

**OTHER MINERAL SUPPLEMENTS**

*Magnesium*

▪ **MAGNESIUM ASPARTATE DIHYDRATE**

Restricted benefit

Hypomagnesaemia

The condition must be documented in the patient's medical records.

**magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50**

4321K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	17.11	6.30	Mag-Sup [PP]
			..	17.68	6.30	Magmin [BB]

▪ **BLOOD AND BLOOD FORMING ORGANS**

▪ **ANTITHROMBOTIC AGENTS**

**ANTITHROMBOTIC AGENTS**

*Platelet aggregation inhibitors excl. heparin*

▪ **ASPIRIN**

**aspirin 100 mg tablet, 112**

10590J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	12.93	6.30	Spren 100 [OW]

**aspirin 100 mg tablet, 90**

4076M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	19.13	6.30	Cardiprin 100 [RC]

▪ **ASPIRIN**

**Note** The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

**aspirin 100 mg enteric tablet, 84**

4077N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	17.43	6.30	Cardasa [AF]	
						<sup>a</sup> Cartia [AS]	<sup>a</sup> Pharmacy Action Low Dose Aspirin [GQ]

## BLOOD AND BLOOD FORMING ORGANS

### aspirin 100 mg enteric capsule, 84

4078P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	18.22	6.30	Astrix [YN]

### ■ CLOPIDOGREL

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

#### Authority required

For use in patients pre- and post-angioplasty

### clopidogrel 75 mg tablet, 28

10169F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	15.18	6.30	<sup>a</sup> Clopidogrel GH [GQ]

### clopidogrel 75 mg tablet, 28

4179Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	15.18	6.30	<sup>a</sup> APO-Clopidogrel [TX]	<sup>a</sup> Blooms the Chemist Clopidogrel [IB]
						<sup>a</sup> Chem mart Clopidogrel [CH]	<sup>a</sup> Clopidogrel AN [EA]
						<sup>a</sup> Iscover [AV]	<sup>a</sup> Piax [AF]
						<sup>a</sup> Plavix [SW]	<sup>a</sup> Terry White Chemists Clopidogrel [TW]

## ■ ANTIANEMIC PREPARATIONS

### IRON PREPARATIONS

*Iron bivalent, oral preparations*

### ■ FERROUS FUMARATE

#### ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60

10594N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	17.76	6.30	Ferro-tab [AE]

*Iron in combination with folic acid*

### ■ FERROUS FUMARATE + FOLIC ACID

#### ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60

10579T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	18.78	6.30	Ferro-f-tab [AE]

### VITAMIN B12 AND FOLIC ACID

*Vitamin B12 (cyanocobalamin and analogues)*

### ■ HYDROXOCOBALAMIN

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B<sub>12</sub> deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

#### Restricted benefit

Pernicious anaemia

#### Restricted benefit

Proven vitamin B12 deficiencies other than pernicious anaemia

#### Restricted benefit

Anaemias associated with vitamin B12 deficiency

#### **Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

### hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

10577Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	15.36	6.30	<sup>a</sup> Vita-B12 [GH]

### hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

10587F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	15.36	6.30	<sup>a</sup> Neo-B12 [PF]

*Folic acid and derivatives*

▪ **FOLIC ACID**

**folic acid 500 microgram tablet, 100**

10584C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*15.15	6.30	<sup>a</sup> Foltabs 500 [PP]	<sup>a</sup> Megafol 0.5 [AF]

▪ **FOLIC ACID**

**Note** The 5 mg strength tablet should be used in malabsorption states only.

**folic acid 5 mg tablet, 100**

10573L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*17.37	6.30	Megafol 5 [AF]

▪ **BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS**

**IRRIGATING SOLUTIONS**

*Salt solutions*

▪ **SODIUM CHLORIDE**

**sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle**

4460R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	14.49	6.30	Baxter Healthcare Pty Ltd [BX]

**sodium chloride 0.9% (9 g/L) solution, 1 L bottle**

4461T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	14.77	6.30	Baxter Healthcare Pty Ltd [BX]

▪ **CARDIOVASCULAR SYSTEM**

▪ **VASOPROTECTIVES**

**AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE**

*Other agents for treatment of hemorrhoids and anal fissures for topical use*

▪ **ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE**

**zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g**

4039N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	18.06	6.30	Anusol [JT]

**zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12**

4040P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	17.12	6.30	Anusol [JT]

▪ **DERMATOLOGICALS**

▪ **ANTIFUNGALS FOR DERMATOLOGICAL USE**

**ANTIFUNGALS FOR TOPICAL USE**

*Antibiotics*

▪ **NYSTATIN**

**nystatin 100 000 units/g cream, 15 g**

4001N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	16.10	6.30	Mycostatin [FM]

*Imidazole and triazole derivatives*

▪ **CLOTRIMAZOLE**

**clotrimazole 1% cream, 20 g**

4004R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	12.85	6.30	<sup>a</sup> Pharmacy Action Anti-Fungal Cream [GQ]
			..	13.19	6.30	<sup>a</sup> Clonea [AF]

## DERMATOLOGICALS

### ▪ KETOCONAZOLE

#### Restricted benefit

Severe seborrhoeic dermatitis

#### ketoconazole 2% shampoo, 100 mL

4007X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	22.35	6.30	Sebizole [EA]

### ▪ MICONAZOLE

#### miconazole nitrate 2% cream, 40 g

3400Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	17.40	6.30	Resolve Thrush [EO]

#### Other antifungals for topical use

### ▪ AMOROLFINE

#### Restricted benefit

Onychomycosis

#### amorolfine 5% application, 5 mL

4010C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	47.65	6.30	<sup>a</sup> Myconail [AE]
			..	61.08	6.30	<sup>a</sup> Sandoz Nail Repair [SZ]
			..	67.73	6.30	<sup>a</sup> Pharmacy Action Anti-Fungal Nail Treatment [GQ]
			..	83.90	6.30	<sup>a</sup> Aporyl [TX]
			..	92.65	6.30	<sup>a</sup> Loceryl [GA]

### ▪ TERBINAFINE

#### Restricted benefit

Tinea pedis

#### terbinafine 1% gel, 15 g

4463X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	25.81	6.30	Lamisil DermGel [GK]

#### terbinafine hydrochloride 1% cream, 15 g

4473K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	24.54	6.30	<sup>a</sup> Lamisil [GK]	<sup>a</sup> Pharmacy Action Pharmsil [GQ]

### ▪ TOLNAFTATE

#### tolnaftate 0.07% spray, 100 g

4481W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.63	6.30	Tinaderm [BN]

## ANTIFUNGALS FOR SYSTEMIC USE

### Antifungals for systemic use

### ▪ TERBINAFINE

#### Authority required

Onychomycosis

#### Clinical criteria:

- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

#### terbinafine 250 mg tablet, 42

4011D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	30.00	6.30	<sup>a</sup> GenRx Terbinafine [GX]	<sup>a</sup> Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
						<sup>a</sup> Tamsil [RW]	<sup>a</sup> Terbinafine GH [GQ]
						<sup>a</sup> Terbinafine Sandoz [SZ]	<sup>a</sup> Tinasil [AF]

## EMOLLIENTS AND PROTECTIVES

### EMOLLIENTS AND PROTECTIVES

#### *Silicone products*

#### ■ DIMETHICONE-350 + GLYCEROL

##### Restricted benefit

For colostomy and ileostomy use

##### Restricted benefit

For use by paraplegic and quadriplegic patients

##### Restricted benefit

For use with surgical appliances

#### dimethicone-350 15% + glycerol 2% cream, 500 g

4551M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	28.47	6.30	Silic 15 [EO]

#### dimethicone-350 15% + glycerol 2% cream, 75 g

4556T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.40	6.30	Silic 15 [EO]

#### *Soft paraffin and fat products*

#### ■ WOOL ALCOHOLS

#### wool alcohols 6% ointment, 100 g

4041Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	17.84	6.30	Eucerin [BE]

#### *Carbamide products*

#### ■ UREA

#### urea 10% cream, 100 g

4042R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	16.11	6.30	Aquacare H.P. [AG]
			..	16.33	6.30	Urederm [KY]
			..	16.61	6.30	Calmurid [OL]

#### *Other emollients and protectives*

#### ■ CARMELLOSE SODIUM + GELATIN + PECTIN

#### carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% oromucosal paste, 5 g

4518T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.81	6.30	Orabase [QA]

#### ■ SKIN EMOLLIENT

#### SKIN EMOLLIENT Lotion 500 mL, 1

4107E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	20.59	6.30	Alpha Keri Lotion [MT]

#### SKIN EMOLLIENT Bath oil 500 mL, 1

4122Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	20.59	6.30	Alpha Keri Bath Oil [MT]
			..	22.69	6.30	QV Bath Oil [EO]
			..	22.77	6.30	Hamilton Skin Therapy Oil [KY]

## PROTECTIVES AGAINST UV-RADIATION

### *Protectives against UV-radiation for topical use*

#### ■ SUNSCREENS

#### SUNSCREENS Lotion (non-alcoholic) 125 mL, 1

4546G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	19.40	6.30	Aquasun Lotion SPF 18 [PF]
			..	21.20	6.30	Sunsense Ultra SPF 50+ [EO]

## DERMATOLOGICALS

### SUNSCREENS Cream 75 g, 1

4307Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	21.20	6.30	Sunsense Sensitive SPF 50+ [EO]

### ■ ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

#### ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

*Anesthetics for topical use*

### ■ LIGNOCAINE

#### lignocaine hydrochloride anhydrous 2% oral liquid, 200 mL

4308R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	103.21	6.30	Xylocaine Viscous [QA]

*Other antipruritics*

### ■ PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE

**Note** For patients who have failed to respond to simple moisturising agents.

#### PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1

4408B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	25.44	6.30	Pinetarsol [EO]

### ■ ANTIPSORIATICS

#### ANTIPSORIATICS FOR TOPICAL USE

*Tars*

### ■ COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR

#### coal tar solution 5% + phenol 0.5% + precipitated sulfur 0.5% gel, 30 g

4505D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	19.44	6.30	Egopsoryl-TA [EO]

### ■ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

#### ANTIBIOTICS FOR TOPICAL USE

*Other antibiotics for topical use*

### ■ MUPIROCIN

#### Restricted benefit

Secondarily infected traumatic skin lesions

#### mupirocin 2% cream, 15 g

4348W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.51	6.30	Bactroban [GK]

#### mupirocin 2% ointment, 15 g

4350Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.51	6.30	Bactroban [GK]

#### CHEMOTHERAPEUTICS FOR TOPICAL USE

*Antivirals*

### ■ PODOPHYLLOTOXIN

#### Authority required

Ano-genital warts

#### podophyllotoxin 0.15% cream, 5 g

4390C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	52.83	6.30	Wartec Cream [GK]

*Other chemotherapeutics*

### ■ INGENOL MEBUTATE

#### Authority required

Solar keratosis

**Clinical criteria:**

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**ingenol mebutate 0.015% gel, 3 x 470 mg**

2464Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	138.90	6.30	Picato [LO]

**■ INGENOL MEBUTATE****Authority required**

Solar (actinic) keratosis

**Clinical criteria:**

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**ingenol mebutate 0.05% gel, 2 x 470 mg**

2468X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	138.90	6.30	Picato [LO]

**■ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS****CORTICOSTEROIDS, PLAIN***Corticosteroids, weak (group I)***■ HYDROCORTISONE ACETATE****Restricted benefit**

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% ointment, 30 g**

10831C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	16.26	6.30	Cortic-DS 1% [QA]

*Corticosteroids, potent (group III)***■ BETAMETHASONE VALERATE****betamethasone (as valerate) 0.1% ointment, 30 g**

4132L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	25.01	6.30	Betnovate [QA]

**betamethasone (as valerate) 0.1% cream, 30 g**

4131K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	25.01	6.30	Betnovate [QA]

**■ MOMETASONE****Note** Application to large areas of skin for longer than four weeks is not recommended.**mometasone furoate 0.1% cream, 50 g**

4342M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	34.62	6.30	Elocon [MK]

**mometasone furoate 0.1% ointment, 50 g**

4343N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	34.62	6.30	Elocon [MK]

**■ ANTISEPTICS AND DISINFECTANTS****ANTISEPTICS AND DISINFECTANTS***Iodine products***■ POVIDONE-IODINE****povidone-iodine 10% solution, 100 mL**

4411E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	24.73	6.30	Betadine Antiseptic Liquid [SW]

## OTHER DERMATOLOGICAL PREPARATIONS

### OTHER DERMATOLOGICAL PREPARATIONS

#### Medicated shampoos

#### COAL TAR SOLUTION + TAR + SALICYLIC ACID

coal tar solution 1% + tar 1% + salicylic acid 2% solution, 250 mL

4447C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	21.89	6.30	Sebitar [EO]

#### SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS

SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1

4560B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	23.23	6.30	Ionil-T [GA]

#### SELENIUM SULFIDE

selenium sulfide 2.5% shampoo, 125 mL

4452H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.80	6.30	Selsun [DQ]

#### TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR

tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL

4405W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	26.50	6.30	Polytar [GK]

#### Wart and anti-corn preparations

#### SALICYLIC ACID + LACTIC ACID

salicylic acid 16.7% + lactic acid 16.7% application, 15 mL

4386W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.29	6.30	Duofilm Solution [GK]

#### Other dermatologicals

#### DICLOFENAC

**Note** Maximum quantity of four tubes (original + 3 repeats) in 12 months.

##### Authority required

Solar (actinic) keratosis

Treatment Phase: Management

##### Clinical criteria:

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

diclofenac sodium 3% gel, 25 g

4046Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	58.15	6.30	Solaraze 3% Gel [FK]

#### ICHTHAMMOL

**Note** For patients who have failed to respond to simple moisturising agents.

ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1

4281H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	21.25	6.30	Egoderm Cream [EO]

#### ICHTHAMMOL + ZINC OXIDE

**Note** For patients who have failed to respond to simple moisturising agents.

ichthammol 1% + zinc oxide 15% ointment, 50 g

4280G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	21.25	6.30	Egoderm Ointment [EO]

▪ **IMIQUIMOD**

**Authority required**

Superficial basal cell carcinoma  
Treatment Phase: Primary treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The condition must be one where other standard treatments are inappropriate, **AND**
- The condition must require topical drug therapy.

**imiquimod 5% cream, 12 x 250 mg sachets**

4559Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	86.62	6.30	<sup>a</sup> Aldiq [QA]	<sup>a</sup> APO-Imiquimod [TX]
			..	88.90	6.30	<sup>a</sup> Aldara [IA]	

▪ **IMIQUIMOD**

**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

**Authority required**

Solar keratosis

**Clinical criteria:**

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**imiquimod 5% cream, 2 x 2 g**

10106X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	91.17	6.30	<sup>a</sup> Aldara Pump [IA]

**imiquimod 5% cream, 12 x 250 mg sachets**

4134N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	86.62	6.30	<sup>a</sup> Aldiq [QA]	<sup>a</sup> APO-Imiquimod [TX]
			..	88.90	6.30	<sup>a</sup> Aldara [IA]	

▪ **LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM**

**light liquid paraffin 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL**

4549K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	23.54	6.30	Hamilton Skin Therapy Wash [KY]

▪ **PANTHENOL**

**Note** To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

**panthenol conditioner, 200 g**

4510J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	17.90	6.30	SebiRinse [EO]

▪ **ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + PURIFIED TALC**

**zinc oxide 25% + maize starch 55.85% + chlorphenesin 1% + purified talc 18.07% dusting powder, 100 g**

4497Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	16.16	6.30	Z.S.C. [RW]

▪ **GENITO URINARY SYSTEM AND SEX HORMONES**

▪ **GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS**

**ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS**

*Antibiotics*

▪ **NYSTATIN**

**nystatin 20 000 units/g vaginal cream, 75 g**

4013F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	17.50	6.30	Nilstat [QA]

*Imidazole derivatives*

## GENITO URINARY SYSTEM AND SEX HORMONES

### ■ CLOTRIMAZOLE

#### clotrimazole 2% vaginal cream, 20 g

4017K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	18.62	6.30	APO-Clotrimazole 3 Day Cream [TX]	Clonea 3 Day Cream [AF]

#### clotrimazole 1% vaginal cream, 35 g

4016J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	17.41	6.30	<sup>a</sup> Clonea 6 Day Cream [AF]	<sup>a</sup> Pharmacy Action FemCream [GQ]
			..	18.62	6.30	<sup>a</sup> APO-Clotrimazole 6 Day Cream [TX]	

### ■ OTHER GYNECOLOGICALS

#### OTHER GYNECOLOGICALS

### ■ ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID

#### acetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g

4434J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	34.12	6.30	Aci-Jel [CU]

### ■ UROLOGICALS

#### UROLOGICALS

##### *Drugs used in erectile dysfunction*

### ■ ALPROSTADIL

#### Authority required

Erectile dysfunction

#### Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

#### Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

#### alprostadil 20 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack

4580C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*125.98	6.30	Caverject Impulse [PF]

#### alprostadil 10 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack

4579B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*101.14	6.30	Caverject Impulse [PF]

### ■ SILDENAFIL

#### Authority required

Erectile dysfunction

#### Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

#### Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

#### sildenafil 25 mg tablet, 4

4584G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	55.04	6.30	<sup>a</sup> Sildenafil Actavis [EA]	<sup>a</sup> Vasafil 25 [RW]
			..	55.05	6.30	<sup>a</sup> Vedafil [AF]	
			..	63.42	6.30	<sup>a</sup> APO-Sildenafil [TX]	
			..	63.42	6.30	<sup>a</sup> Viagra [PF]	

**sildenafil 100 mg tablet, 4**

4586J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	71.61	6.30	<sup>a</sup> APO-Sildenafil [TX] <sup>a</sup> Sildenafil Actavis [EA] <sup>a</sup> Terry White Chemists Sildenafil [TW] <sup>a</sup> Vedafile [AF]	<sup>a</sup> Chem mart Sildenafil [CH] <sup>a</sup> Sildenafil generichealth [GQ] <sup>a</sup> Vasafil 100 [RW]
			..	83.14	6.30	<sup>a</sup> Silaran [RA]	<sup>a</sup> Viagra [PF]

**sildenafil 50 mg tablet, 4**

4585H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	67.04	6.30	<sup>a</sup> APO-Sildenafil [TX] <sup>a</sup> Vasafil 50 [RW]	<sup>a</sup> Sildenafil Actavis [EA] <sup>a</sup> Vedafile [AF]
			..	77.70	6.30	<sup>a</sup> Viagra [PF]	

**■ TADALAFIL**
**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**tadalafil 20 mg tablet, 4**

4597Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	103.85	6.30	Cialis [LY]

**tadalafil 10 mg tablet, 4**

4596X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	103.85	6.30	Cialis [LY]

**■ VARDENAFIL**
**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**vardenafil 20 mg tablet, 4**

4302K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	81.18	6.30	Levitra [BN]

**vardenafil 10 mg tablet, 4**

4290T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	71.43	6.30	Levitra [BN]

*Other urologicals*
**■ BICARBONATE + CITRIC ACID + TARTARIC ACID**
**Restricted benefit**

Urinary symptoms

**Clinical criteria:**

- The treatment must be for when antibiotic or other therapy alone is inappropriate.

**sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets**

4049D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	4	..	17.29	6.30	Uracol [EA]	Ural Sachets [QA]

**DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY**

*Alpha-adrenoreceptor antagonists*

▪ **ALFUZOSIN**

Authority required

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**alfuzosin hydrochloride 10 mg modified release tablet, 30**

4277D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	1	5	..	62.85	6.30	Xatral SR [SW]	

▪ **DUTASTERIDE + TAMSULOSIN**

Authority required

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

10102Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	1	5	..	31.97	6.30	Duodart 500ug/400ug [GK]	

▪ **TAMSULOSIN**

Authority required

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**tamsulosin hydrochloride 400 microgram modified release tablet, 30**

4070F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	62.85	6.30	Flomaxtra [LS]	Tamsulosin Sandoz SR [SZ]

*Testosterone-5-alpha reductase inhibitors*

▪ **DUTASTERIDE**

Authority required

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**dutasteride 500 microgram capsule, 30**

10095H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	1	5	..	27.76	6.30	Avodart [GK]	

▪ **FINASTERIDE**

Authority required

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**finasteride 5 mg tablet, 30**

4233T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	75.88	6.30	<sup>a</sup> Auro-Finasteride [DO]	<sup>a</sup> Finasteride AN [EA]
						<sup>a</sup> Finasteride GH 5 [GQ]	<sup>a</sup> Finide [AL]
			..	93.73	6.30	<sup>a</sup> Finnacar [RW]	
			..	98.08	6.30	<sup>a</sup> APO-Finasteride [TX]	<sup>a</sup> Finasta [SZ]
						<sup>a</sup> Finasteride Alphapharm [AF]	<sup>a</sup> Finasteride-GA 5 [GN]
						<sup>a</sup> Pharmacor Finasteride 5 [CR]	<sup>a</sup> Proscar [MK]

**finasteride 5 mg tablet, 28**

4303L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	88.22	6.30	<sup>a</sup> Finpro [RZ]	<sup>a</sup> Pharmacy Choice Finasteride [RI]

**ANTIINFECTIVES FOR SYSTEMIC USE**
**ANTIBACTERIALS FOR SYSTEMIC USE**
**MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS**
*Macrolides*
**AZITHROMYCIN**
**Restricted benefit**

Upper and lower respiratory tract infections

**azithromycin 500 mg tablet, 3**

4115N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	32.91	6.30	Zedd 500 [RW]	
						<sup>a</sup> APO-Azithromycin [TX]	<sup>a</sup> Azithromycin-GA [EA]
						<sup>a</sup> Azithromycin Sandoz [SZ]	<sup>a</sup> Chem mart Azithromycin [CH]
						<sup>a</sup> Terry White Chemists Azithromycin [TW]	<sup>a</sup> Zithromax [PF]
						<sup>a</sup> Zitrocin [GN]	

**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**
**ANTINEOPLASTIC AGENTS**
**ANTIMETABOLITES**
*Pyrimidine analogues*
**FLUOROURACIL**
**fluorouracil 5% cream, 20 g**

4222F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	65.28	6.30	<sup>a</sup> APOC-5FU [TX]	<sup>a</sup> Efudix [IA]

**IMMUNOSUPPRESSANTS**
**IMMUNOSUPPRESSANTS**
*Tumor necrosis factor alpha (TNF-) inhibitors*
**INFLIXIMAB**

**Note** Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998

Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

**Authority required**

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

(1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and

(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;

(2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;

(3) No history of active tuberculosis requiring treatment in the last 3 years;

(4) No history of opportunistic infection in the last 2 months;

(5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

**Authority required**

## MUSCULO-SKELETAL SYSTEM

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

- (1) There is improvement in ESR and/or CRP; and
- (2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

### infliximab 100 mg injection, 1 vial

4284L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	569.47	6.30	Remicade [JC]

## ■ MUSCULO-SKELETAL SYSTEM

### ■ TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

#### TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

##### *Preparations with salicylic acid derivatives*

### ■ EUCALYPTUS OIL + MENTHOL + METHYL SALICYLATE

#### eucalyptus oil 10% + menthol 4% + methyl salicylate 25% cream, 100 g

4022Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	17.70	6.30	Gold Cross [BI]

### ■ METHYL SALICYLATE

#### methyl salicylate 50% ointment, 100 g

4023R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	16.09	6.30	Gold Cross [BI]

#### methyl salicylate 25% liniment, 100 mL

4026X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	14.15	6.30	Gold Cross [BI]

## ■ DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

#### *Bisphosphonates*

### ■ RISEDRONATE

#### Authority required

Preservation of bone mineral density

#### Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).  
Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

#### risedronate sodium 35 mg tablet, 4

4444X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	35.10	6.30	<sup>a</sup> Acris Once-a-Week [AF] <sup>a</sup> Risedronate AN [EA] <sup>a</sup> Risedronate Sandoz [SZ]	<sup>a</sup> APO-Risedronate [TX] <sup>a</sup> Risedronate-GA [GN] <sup>a</sup> Risedro once a week [RW]

#### RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4

2191H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	35.10	6.30	Actonel EC [UA]

#### risedronate sodium 5 mg tablet, 28

4443W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	35.10	6.30	Actonel [UA]

#### *Bisphosphonates, combinations*

▪ **ALENDRONATE + COLECALCIFEROL**

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).  
Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**alendronate 70 mg + colecalciferol 140 microgram tablet, 4**

2224C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	17.94	6.30	<sup>a</sup> Alendronate plus D3-DRLA [RZ]	<sup>a</sup> APO-Alendronate Plus D3 70 mg/140 mcg [TX]
						<sup>a</sup> Chem mart Alendronate Plus D3 70 mg/140 mcg [CH]	<sup>a</sup> FonatPlus [AF]
						<sup>a</sup> Terry White Chemists Alendronate Plus D3 70 mg/140 mcg [TW]	
			..	20.20	6.30	<sup>a</sup> Fosamax Plus 70 mg/140 mcg [MK]	

**alendronate 70 mg + colecalciferol 70 microgram tablet, 4**

2194L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	17.94	6.30	<sup>a</sup> Alendronate plus D3-DRLA [RZ]	<sup>a</sup> APO-Alendronate Plus D3 70 mg/70 mcg [TX]
						<sup>a</sup> Chem mart Alendronate Plus D3 70 mg/70 mcg [CH]	<sup>a</sup> FonatPlus [AF]
						<sup>a</sup> Terry White Chemists Alendronate Plus D3 70 mg/70 mcg [TW]	
			..	20.20	6.30	<sup>a</sup> Fosamax Plus [MK]	

▪ **ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).  
Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack**

2273P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	22.83	6.30	<sup>a</sup> APO-Alendronate Plus D3 and Calcium [TX]
			..	24.71	6.30	<sup>a</sup> Fosamax Plus D-Cal [MK]

▪ **RISEDRONATE (&) CALCIUM CARBONATE**

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).  
Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1**

2220W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	35.10	6.30	Actonel EC Combi [UA]

**risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28**

4059P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	35.10	6.30	Acris Combi [AF]

RPBS

## NERVOUS SYSTEM

### ■ RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL

#### Authority required

Preservation of bone mineral density

#### Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).  
Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1**

2254P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	35.10	6.30	Actonel EC Combi D [UA]

## ■ NERVOUS SYSTEM

### ■ ANALGESICS

#### OPIOIDS

*Natural opium alkaloids*

### ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- chronic severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

#### Restricted benefit

Chronic severe disabling pain

#### Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 200 mg modified release tablet, 28**

4349X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	116.58	6.30	MS Contin [MF]

*Opioids in combination with non-opioid analgesics*

### ■ ASPIRIN + CODEINE

**aspirin 300 mg + codeine phosphate 8 mg dispersible tablet, 40**

4286N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	17.84	6.30	Aspalgin 40 [QA]

### ■ PARACETAMOL + CODEINE

**paracetamol 500 mg + codeine phosphate 8 mg tablet, 40**

4275B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	14.80	6.30	Panamax Co. 40 [SW]

**paracetamol 500 mg + codeine phosphate hemihydrate 15 mg tablet, 20**

10186D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	13.97	6.30	Pharmacy Action Paracetamol Plus Codeine [GQ]

## OTHER ANALGESICS AND ANTIPYRETICS

*Anilides*

### ■ PARACETAMOL

**paracetamol 240 mg/5 mL oral liquid, 200 mL**

10599W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	14.79	6.30	Panamax 240 Elixir [SW]

**paracetamol 500 mg tablet, 100**

10582Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	12.74	6.30	<sup>a</sup> APO-Paracetamol [TX]	<sup>a</sup> Febridol [EA]

<sup>a</sup> Generic Health Pty Ltd [GQ] <sup>a</sup> Panamax [SW]  
<sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Paralgin [OW]  
<sup>a</sup> Parapane [AF]

▪ **PARACETAMOL**

**Restricted benefit**

Persistent pain

**Clinical criteria:**

- The condition must be associated with osteoarthritis.

**paracetamol 665 mg modified release tablet, 96**

10598T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*18.55	6.30	Osteomol 665 Paracetamol [CR]

▪ **PARACETAMOL**

**Restricted benefit**

Chronic arthropathies

**paracetamol 500 mg tablet, 100**

10585D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	4	..	*16.03	6.30	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Generic Health Pty Ltd [GQ] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Parapane [AF]	<sup>a</sup> Febridol [EA] <sup>a</sup> Panamax [SW] <sup>a</sup> Paralgin [OW]

*Other analgesics and antipyretics*

▪ **GABAPENTIN**

**Authority required**

Refractory neuropathic pain

**Clinical criteria:**

- The condition must be unable to be controlled by other drugs.

**gabapentin 100 mg capsule, 100**

4591P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	15.13	6.30	<sup>a</sup> APO-Gabapentin [TX] <sup>a</sup> Neurontin [PF]	<sup>a</sup> Gabapentin Aspen 100 [RW] <sup>a</sup> Nupentin 100 [AF]

**gabapentin 400 mg capsule, 100**

4593R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	29.50	6.30	<sup>a</sup> Gabapentin 400 [CR] <sup>a</sup> Gabapentin GH [GQ] <sup>a</sup> GenRx Gabapentin [GX] <sup>a</sup> Nupentin 400 [AF]	<sup>a</sup> Gabapentin Aspen 400 [RW] <sup>a</sup> Gantin [EA] <sup>a</sup> Neurontin [PF]

**gabapentin 600 mg tablet, 100**

4594T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	40.31	6.30	<sup>a</sup> Gabapentin AN [EA] <sup>a</sup> GenRx Gabapentin [GX] <sup>a</sup> Nupentin Tabs [AF]	<sup>a</sup> Gabapentin Aspen 600 [RW] <sup>a</sup> Neurontin [PF]

**gabapentin 300 mg capsule, 100**

4592Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	24.59	6.30	<sup>a</sup> Gabapentin 300 [CR] <sup>a</sup> Gabapentin GH [GQ] <sup>a</sup> GenRx Gabapentin [GX] <sup>a</sup> Nupentin 300 [AF]	<sup>a</sup> Gabapentin Aspen 300 [RW] <sup>a</sup> Gantin [EA] <sup>a</sup> Neurontin [PF]

**gabapentin 800 mg tablet, 100**

4595W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	50.06	6.30	<sup>a</sup> Gabapentin AN [EA] <sup>a</sup> Gantin [ED] <sup>a</sup> Neurontin [PF]	<sup>a</sup> Gabapentin Aspen 800 [RW] <sup>a</sup> GenRx Gabapentin [GX] <sup>a</sup> Nupentin Tabs [AF]

▪ **PSYCHOLEPTICS**

**ANXIOLYTICS**

*Benzodiazepine derivatives*

## NERVOUS SYSTEM

### ▪ BROMAZEPAM

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

#### Authority required

Terminal disease

#### **Clinical criteria:**

- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

#### Authority required

Refractory phobic or anxiety states

#### **Clinical criteria:**

- The treatment must be for the short-term.

#### **bromazepam 6 mg tablet, 30**

4151L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*36.89	6.30	Lexotan [RO]

#### **bromazepam 3 mg tablet, 30**

4150K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*31.15	6.30	Lexotan [RO]

### *Azaspirodecanedione derivatives*

### ▪ BUSPIRONE

#### Authority required

Anxiety

#### **Clinical criteria:**

- The treatment must be for the short-term.

#### **buspirone hydrochloride 5 mg tablet, 50**

4144D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	38.54	6.30	Buspar [QA]

#### **buspirone hydrochloride 10 mg tablet, 50**

4145E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	55.01	6.30	Buspar [QA]

## HYPNOTICS AND SEDATIVES

### *Benzodiazepine derivatives*

### ▪ FLUNITRAZEPAM

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

#### Authority required

Terminal disease

#### **Clinical criteria:**

- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

#### Authority required

Refractory phobic or anxiety states

#### **Clinical criteria:**

- The treatment must be for the short-term.

#### **flunitrazepam 1 mg tablet, 30**

4216X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	19.10	6.30	Hypnodorm [AF]

### *Benzodiazepine related drugs*

### ▪ ZOPICLONE

#### Restricted benefit

Insomnia

#### **Clinical criteria:**

- The treatment must be for the short-term.

**zopiclone 7.5 mg tablet, 30**

4522B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	24.43	6.30	<sup>a</sup> APO-Zopiclone [TX] <sup>a</sup> Imrest [AF]	<sup>a</sup> Chem mart Zopiclone [CH] <sup>a</sup> Terry White Chemists Zopiclone [TW]
			..	27.17	6.30	<sup>a</sup> Zopiclone GH [GQ] <sup>a</sup> Imovane [SW]	

■ **OTHER NERVOUS SYSTEM DRUGS**

**DRUGS USED IN ADDICTIVE DISORDERS**

*Drugs used in nicotine dependence*

■ **NICOTINE**

**Note** Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

**Authority required**

Nicotine dependence

**Clinical criteria:**

- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must have entered a comprehensive support and counselling program.

**nicotine 7 mg/24 hours patch, 7**

4571N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*51.57	6.30	QuitX [AF]

**nicotine 14 mg/24 hours patch, 7**

4572P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*54.73	6.30	QuitX [AF]
			..	*67.75	6.30	Nicabate CQ 14 [GC]

**nicotine 5 mg/16 hours patch, 7**

4576W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*50.97	6.30	Nicorette Patch [JT]

**nicotine 10 mg/16 hours patch, 7**

4577X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*54.95	6.30	Nicorette Patch [JT]

**nicotine 15 mg/16 hours patch, 7**

4578Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*59.77	6.30	Nicorette Patch [JT]

**nicotine 21 mg/24 hours patch, 7**

4573Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*57.69	6.30	QuitX [AF]
			..	*67.75	6.30	Nicabate CQ 21 [GC]

■ **ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS**

■ **ANTHELMINTICS**

**ANTINEMATODAL AGENTS**

*Benzimidazole derivatives*

■ **MEBENDAZOLE**

**mebendazole 100 mg tablet, 6**

4325P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	17.29	6.30	Pharmacy Action Worm Treatment [GQ]

■ **RESPIRATORY SYSTEM**

■ **NASAL PREPARATIONS**

**DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE**

*Sympathomimetics, plain*

## RESPIRATORY SYSTEM

### ■ OXYMETAZOLINE

#### oxymetazoline hydrochloride 0.05% nasal spray, 18 mL

4379L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.08	6.30	Logicin Rapid Relief [QA]

#### oxymetazoline hydrochloride 0.05% nasal spray, 15 mL

4378K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.42	6.30	Drixine [BN]

*Antiallergic agents, excl. corticosteroids*

### ■ CROMOGLYCATE

#### sodium cromoglycate 2% nasal spray, 26 mL

4468E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	25.43	6.30	Rynacrom [SW]

### ■ LEVOCABASTINE

#### levocabastine 0.05% nasal spray, 100 actuations

4311X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	21.37	6.30	Livostin [JT]

*Corticosteroids*

### ■ BUDESONIDE

#### Restricted benefit

Severe intractable rhinitis

#### budesonide 64 microgram/actuation nasal spray, 120 actuations

4092J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	41.68	6.30	Budamax Aqueous [PM]

*Other nasal preparations*

### ■ IPRATROPIUM

#### Restricted benefit

Severe intractable rhinorrhoea

#### Clinical criteria:

- The condition must be associated with perennial rhinitis, **AND**
- The condition must be unresponsive to insufflated nasal steroids.

#### ipratropium bromide monohydrate 22 microgram/actuation nasal spray, 180 actuations

4089F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	26.48	6.30	Atrovent Nasal Aqueous [VZ]

#### ipratropium bromide monohydrate 44 microgram/actuation nasal spray, 180 actuations

4090G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	32.63	6.30	Atrovent Nasal Forte [VZ]

## NASAL DECONGESTANTS FOR SYSTEMIC USE

*Sympathomimetics*

### ■ PSEUDOEPHEDRINE

#### pseudoephedrine hydrochloride 60 mg tablet, 12

4029C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	14.44	6.30	<sup>a</sup> Pharmacy Action Sinus & Nasal Decongestant Relief [GQ]
			..	15.09	6.30	<sup>a</sup> Logicin Sinus [QA]

### ■ COUGH AND COLD PREPARATIONS

#### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

*Expectorants*

**■ AMMONIUM + SENEGA ROOT**
**ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL**

4074K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	4	..	13.49	6.30	Gold Cross [BI]

**COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS**
*Opium alkaloids and derivatives*
**■ PHOLCODINE**
**pholcodine 1 mg/mL oral liquid, 100 mL**

4071G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	13.35	6.30	Gold Cross [BI]
			..	18.21	6.30	Duro-Tuss [IA]

**■ ANTIHISTAMINES FOR SYSTEMIC USE**
**ANTIHISTAMINES FOR SYSTEMIC USE**
*Piperazine derivatives*
**■ CETIRIZINE**
**cetirizine hydrochloride 10 mg tablet, 30**

4175R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	28.06	6.30	<sup>a</sup> Pharmacy Action Cetrelief [GQ]
			..	31.29	6.30	<sup>a</sup> Alzene [AF]
			..	34.09	6.30	Zilarex [SZ]
			..	39.81	6.30	<sup>a</sup> Zyrtec [JT]

*Other antihistamines for systemic use*
**■ FEXOFENADINE**
**fexofenadine hydrochloride 120 mg tablet, 30**

4238C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	27.88	6.30	<sup>a</sup> Pharmacy Action Fexorelief 120 [GQ]
			..	31.09	6.30	<sup>a</sup> Xergic [AF]
			..	35.69	6.30	<sup>a</sup> Fexal [SZ]
			..	47.30	6.30	<sup>a</sup> Telfast 120 [SW]

**fexofenadine hydrochloride 60 mg tablet, 20**

4237B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*55.15	6.30	Telfast [SW]

**■ LORATADINE**
**loratadine 10 mg tablet, 30**

4313B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	30.49	6.30	<sup>a</sup> Pharmacy Action Lorastyne [GQ]
			..	34.19	6.30	<sup>a</sup> Allereze [AF]
			..	43.82	6.30	<sup>a</sup> Lorano [SZ]
			..	46.09	6.30	<sup>a</sup> Claratyne [BN]

**■ SENSORY ORGANS**
**■ OPHTHALMOLOGICALS**
**DECONGESTANTS AND ANTIALLERGICS**
*Sympathomimetics used as decongestants*
**■ NAPHAZOLINE**
**naphazoline hydrochloride 0.1% eye drops, 15 mL**

4035J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	18.63	6.30	Albalon Liquifilm [AG]

## VARIOUS

### ▪ NAPHAZOLINE + ANTAZOLINE

naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL

4032F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	18.38	6.30	Albalon-A [AG]

*Other antiallergics*

### ▪ LEVOCABASTINE

levocabastine 0.05% eye drops, 4 mL

4310W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	21.37	6.30	Livostin [JT]

## ▪ OTOLOGICALS

### OTHER OTOLOGICALS

*Indifferent preparations*

### ▪ CARBAMIDE PEROXIDE

carbamide peroxide 6.5% ear drops, 12 mL

4176T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.57	6.30	Ear Clear for Ear Wax Removal [KY]

### ▪ DICHLOROBENZENE WITH CHLORBUTOL AND ARACHIS OIL

DICHLOROBENZENE with CHLORBUTOL and ARACHIS OIL Ear drops, ortho-dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL, 1

4180B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.75	6.30	Cerumol [UN]

### ▪ DOCUSATE

docusate sodium 0.5% ear drops, 10 mL

4199B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.09	6.30	Waxsol [HM]

## ▪ VARIOUS

### ▪ ALL OTHER THERAPEUTIC PRODUCTS

#### ALL OTHER THERAPEUTIC PRODUCTS

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

### ▪ SODIUM POLYSTYRENE SULFONATE

sodium polystyrene sulfonate 999.3 mg/g powder, 454 g

4470G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	69.91	6.30	Resonium-A [SW]

## ▪ GENERAL NUTRIENTS

### OTHER NUTRIENTS

*Other combinations of nutrients*

### ▪ PROTEIN FORMULA WITH ARGININE, VITAMIN C AND E

#### Restricted benefit

Stage 2 and above pressure injury

#### Clinical criteria:

- The treatment must be for special medical purposes to support healing of pressure injuries.

protein formula with arginine, vitamin C and E powder for oral liquid, 14 x 9.2 g sachets

10850C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*158.63	6.30	Arginaid [NT]

### ▪ PROTEIN FORMULA WITH ARGININE, VITAMIN C, E AND ZINC

#### Restricted benefit

Stage 2 and above pressure injury

**Clinical criteria:**

- The treatment must be for special medical purposes to support healing of pressure injuries.

**protein formula with arginine, vitamin C, E and zinc oral liquid, 27 x 237 mL cartons**

10841N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*263.19	6.30	Arginaid Extra [NT]

## ALL OTHER NON-THERAPEUTIC PRODUCTS

### ALL OTHER NON-THERAPEUTIC PRODUCTS

#### LUBRICATING AGENT

**lubricating agent jelly, 100 g**

4306P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	14.32	6.30	Lubri-Gel [PP]

#### Other non-therapeutic auxiliary products

#### BANDAGE ABSORBENT WOOL

**bandage absorbent wool 10 cm x 3 m bandage, 1**

4653X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	23.18	6.30	Surepress 650948 [CC]

#### BANDAGE CALICO

**bandage calico large triangular bandage, 1**

4717G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.10	6.30	Handy 36361414 [BV]

#### BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1**

4654Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*76.90	6.30	Comprilan 01027-00 [BV]

**bandage compression 10 cm x 3 m high stretch bandage, 1**

4748X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*71.55	6.30	Surepress 650947 [CC]
			..	*149.85	6.30	Tensopress 71723-00 [BV]

#### BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**bandage compression four layer bandage, 1**

4598B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*164.15	6.30	Profore Lite 66050415 [SN]

**bandage compression four layer bandage, 1**

4658E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*244.65	6.30	Profore 66050016 [SN]

#### BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage compression 10 cm x 3.5 m high stretch bandage, 1**

4657D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*76.70	6.30	Setopress 3505 [MH]

▪ **BANDAGE COMPRESSION**

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

**Restricted benefit**

Venous ulcer

Treatment Phase: Initial treatment

**Restricted benefit**

Venous ulcer

Treatment Phase: Continuing treatment

**bandage compression two layer bandage, 1**

4050E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	42.85	6.30	Coban 2 [MM]

▪ **BANDAGE RETENTION COHESIVE HEAVY**

**bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1**

4811F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*17.69	6.30	Peg 7420 [MM]

**bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1**

4812G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*20.55	6.30	Peg 7422 [MM]

**bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1**

4814J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*30.01	6.30	Peg 7425 [MM]

**bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1**

4813H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*23.83	6.30	Peg 7423 [MM]

**bandage retention cohesive heavy 10 cm x 2 m bandage, 1**

4660G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*22.35	6.30	Coban 1584 [MM]

▪ **BANDAGE RETENTION COHESIVE LIGHT**

**bandage retention cohesive light 6 cm x 2 m bandage, 1**

4719J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*19.61	6.30	Handygauze Cohesive 8633 [BV]

**bandage retention cohesive light 10 cm x 2 m bandage, 1**

4662J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*33.47	6.30	Handygauze Cohesive 8635 [BV]

**bandage retention cohesive light 2.5 cm x 2 m bandage, 2**

4718H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.23	6.30	Handygauze Cohesive 8631 [BV]

▪ **BANDAGE RETENTION COTTON CREPE**

**bandage retention cotton crepe 10 cm x 2.3 m bandage, 1**

4729X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.57	6.30	Telfa 8254F [KE]
				*33.01	6.30	Tensocrepe 36301001 [BV]

**bandage retention cotton crepe 5 cm x 2.3 m bandage, 1**

4727T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*20.65	6.30	Telfa 8252F [KE]
				*23.31	6.30	Tensocrepe 36300501 [BV]

**bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1**

4728W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*24.83	6.30	Telfa 8253F [KE]

.. \*27.87 6.30 Tensocrepe 36307501 [BV]

## ▪ BANDAGE TUBULAR

### bandage tubular size E (35 cm to 45 cm) straight bandage, 1

4665M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.89	6.30	Elastoplast 2227 [BE]

### bandage tubular size C (15 cm to 25 cm) straight bandage, 1

4663K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.89	6.30	Elastoplast 2225 [BE]

### bandage tubular size D (25 cm to 43 cm) straight bandage, 1

4664L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.89	6.30	Elastoplast 2226 [BE]

## ▪ BANDAGE TUBULAR

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

### bandage tubular 6.25 cm x 1 m bandage, 1

4855M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.53	6.30	Tubigrip B 1520 [MH]

### bandage tubular 8.75 cm x 1 m bandage, 1

4858Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.53	6.30	Tubigrip E 1547 [MH]

### bandage tubular 6.75 cm x 1 m bandage, 1

4856N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.53	6.30	Tubigrip C 1545 [MH]

### bandage tubular 10 cm x 1 m bandage, 1

4859R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.53	6.30	Tubigrip F 1548 [MH]

### bandage tubular 7.5 cm x 1 m bandage, 1

4857P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.53	6.30	Tubigrip D 1546 [MH]

## ▪ BANDAGE TUBULAR FINGER

### BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1

4798M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.96	6.30	TubeGauz 0501633 [SS]

## ▪ BANDAGE TUBULAR LIGHT WEIGHT

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

### bandage tubular light weight 10 m medium limb size bandage, 1

4672X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	28.74	6.30	Tubifast 2436 [MH]

### bandage tubular light weight 10 m small limb size bandage, 1

4671W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	25.30	6.30	Tubifast 2434 [MH]

### bandage tubular light weight 10 m large limb size bandage, 1

4673Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	29.97	6.30	Tubifast 2438 [MH]

▪ **BANDAGE TUBULAR LONG STOCKING**

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular long stocking small size bandage, 1**

4674B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*37.79	6.30	Tubigrip 1482 [MH]

**bandage tubular long stocking XX/large size bandage, 1**

4675C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*37.81	6.30	Tubigrip 1486 [MH]

**bandage tubular long stocking large size bandage, 1**

4799N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*37.79	6.30	Tubigrip 1484 [MH]

**bandage tubular long stocking medium size bandage, 1**

4797L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*37.79	6.30	Tubigrip 1483 [MH]

▪ **BANDAGE TUBULAR SHORT STOCKING**

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular short stocking medium C/D size bandage, 1**

4815K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.57	6.30	Tubigrip 1480 [MH]

**bandage tubular short stocking small B/C size bandage, 1**

4661H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.57	6.30	Tubigrip 1479 [MH]

**bandage tubular short stocking large D/E size bandage, 1**

4816L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.57	6.30	Tubigrip 1481 [MH]

▪ **BANDAGE ZINC PASTE**

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**bandage zinc paste 10 cm x 9.1 m bandage, 1**

4670T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*30.53	6.30	Flexidress 650941 [CC]

▪ **BANDAGE ZINC PASTE**

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage zinc paste 7.5 cm x 6 m bandage, 1**

4669R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*31.29	6.30	Steripaste 3610 [MH]

▪ **BANDAGE ZINC PASTE**

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**bandage zinc paste 7.5 cm x 6 m bandage, 1**

4750B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*86.29	6.30	Viscopaste 4948 [SN]

**bandage zinc paste 80 cm (stockings) bandage, 4**

4760M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	98.90	6.30	ZipZoc 66000747 [SN]

**▪ BETAINES + POLYAMINOPROPYL BIGUANIDE****betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules**

2525X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	28.70	6.30	Prontosan Wound Irrigation Solution [BR]

**▪ CADEXOMER-IODINE**

**Note** Suitable for yellow sloughy infected and malodorous wounds.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**cadexomer-iodine 50% ointment, 4 x 10 g**

4932N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	118.06	6.30	Iodosorb Ointment 66051240 [SN]

**DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1**

4937W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	168.09	6.30	Iodosorb 66051360 [SN]

**DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1**

4935R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	111.81	6.30	Iodosorb 66051330 [SN]

**cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet**

4936T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	159.73	6.30	Iodosorb 66051340 [SN]

**cadexomer-iodine 50% ointment, 2 x 20 g**

4933P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	117.00	6.30	Iodosorb Ointment 66051230 [SN]

**cadexomer-iodine 3 g sterile dusting powder, 7 sachets**

4931M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	74.91	6.30	Iodosorb Powder 66051070 [SN]

**▪ DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND****dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1**

4681J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*96.95	6.30	Actisorb Plus MAP105 [KI]

**dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5**

4743P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	86.95	6.30	CarboFLEX 403204 [CC]

**dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10**

4742N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	77.05	6.30	CarboFLEX 403202 [CC]

**▪ DRESSING ALGINATE CAVITY WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5**

1905G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*110.03	6.30	Kaltostat 168117 [CC]

**DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1**

4832H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*104.45	6.30	Sorbsan 1411 [UM]

▪ **DRESSING ALGINATE CAVITY WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g**

4682K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*130.45	6.30	Comfeel SeaSorb Filler 3740 [CT]

▪ **DRESSING ALGINATE SUPERFICIAL WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10**

4683L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	88.05	6.30	Kaltostat 168212 [CC]

▪ **DRESSING ALGINATE SUPERFICIAL WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing alginate superficial wound 10 cm x 10 cm dressing, 10**

4700J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	113.67	6.30	Algisite M 66000520 [SN]

**dressing alginate superficial wound 15 cm x 20 cm dressing, 10**

4691X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	273.44	6.30	Algisite M 66000521 [SN]

**dressing alginate superficial wound 5 cm x 5 cm dressing, 10**

4699H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	49.57	6.30	Kaltostat 168210 [CC]
			..	60.59	6.30	Algisite M 66000519 [SN]

▪ **DRESSING ALGINATE SUPERFICIAL WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing alginate superficial wound 10 cm x 10 cm dressing, 1**

4831G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*81.95	6.30	Sorbsan 1410 [UM]
			..	*87.15	6.30	Comfeel SeaSorb Dressing 3710 [CT]

**dressing alginate superficial wound 5 cm x 5 cm dressing, 1**

4684M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*47.05	6.30	Comfeel SeaSorb Dressing 3705 [CT]

**▪ DRESSING ALGINATE WITH MANUKA HONEY**

**Note** Suitable for yellow sloughy infected and malodorous wounds.

**dressing alginate with manuka honey 2.5 cm x 20 cm ribbon, 5**

10857K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	4	..	114.85	6.30	Algivon Plus Ribbon & Probe CR4231 [DJ]

**dressing alginate with manuka honey 10 cm x 10 cm dressing, 5**

10849B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	4	..	63.56	6.30	Algivon Plus CR4225 [DJ]

**▪ DRESSING FILM****dressing film 6 cm x 7 cm dressing, 8**

4686P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.11	6.30	Nexcare Tegaderm Transparent H1624 [MM]

**dressing film 10 cm x 12 cm dressing, 4**

4687Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	22.59	6.30	Nexcare Tegaderm Transparent H1626 [MM]

**dressing film 15 cm x 20 cm dressing, 1**

4688R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	..	..	*32.17	6.30	Tegaderm Transparent 1628 [MM]

**▪ DRESSING FILM**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing film 10 cm x 12 cm dressing, 10**

4893M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	37.41	6.30	Op-Site Flexigrd 4629 [SN]

**▪ DRESSING FILM ISLAND****dressing film island 5 cm x 7 cm dressing, 1**

4689T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*19.55	6.30	Tegaderm Transparent Island 3582 [MM]

**dressing film island 9 cm x 10 cm dressing, 1**

4690W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*29.55	6.30	Tegaderm Transparent Island 3586 [MM]

**▪ DRESSING FILM ISLAND**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing film island 5 cm x 7.2 cm dressing, 5**

4898T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*32.65	6.30	Cutifilm Plus 36361370 [SN]

**dressing film island 8 cm x 10 cm dressing, 5**

4899W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*49.21	6.30	Cutifilm Plus 36361371 [SN]

**▪ DRESSING FOAM HEAVY EXUDATE**

**Note** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam heavy exudate 10 cm x 10 cm dressing, 10**

4795J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	137.01	6.30	Allevyn 66007637 [SN]

**▪ DRESSING FOAM MODERATE EXUDATE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam moderate exudate cavity conforming foam, 20 g sachet**

4694C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	98.92	6.30	Cavicare 4563 [SN]

**▪ DRESSING FOAM MODERATE EXUDATE**

**Note** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10**

4590N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	141.33	6.30	Allevyn Adhesive 66000044 [SN]

**▪ DRESSING FOAM WITH SILICONE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10**

10029W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	85.30	6.30	Allevyn Life 66801068 [SN]

**dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10**

10017F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	60.55	6.30	Allevyn Life 66801067 [SN]

**dressing foam with silicone 21 cm x 21 cm dressing, 10**

10021K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	232.10	6.30	Allevyn Life 66801070 [SN]

**dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10**

10023M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	116.86	6.30	Allevyn Life 66801069 [SN]

**▪ DRESSING FOAM WITH SILICONE AND SILVER**

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressings foam with silicone and silver 10 cm x 10 cm dressing, 5**

2439J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	104.62	6.30	Mepilex Ag [MH]

**dressings foam with silicone and silver 10 cm x 10 cm dressing, 5**

2470B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	111.67	6.30	Mepilex Border Ag [MH]

**▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressings foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10**

4207K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	57.32	6.30	Allevyn Gentle Border 66800269 [SN]

**dressings foam with silicone heavy exudate 10 cm x 10 cm dressing, 10**

4196W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	80.43	6.30	Allevyn Gentle 66800248 [SN]

**dressings foam with silicone heavy exudate 10 cm x 10 cm dressing, 10**

4230P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	80.43	6.30	Allevyn Gentle Border 66800270 [SN]

**▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE**

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**dressings foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 5**

4642H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	32.26	6.30	Mepilex Border 295200 [MH]

**dressings foam with silicone heavy exudate 10 cm x 10 cm dressing, 5**

4643J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	42.85	6.30	Mepilex Border 295300 [MH]

**▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE**

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**dressings foam with silicone light exudate 6 cm x 8.5 cm dressing, 5**

4644K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	29.91	6.30	Mepilex Lite 284000 [MH]

**dressings foam with silicone light exudate 10 cm x 10 cm dressing, 5**

4645L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	38.73	6.30	Mepilex Lite 284100 [MH]

**▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE**

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5**

4626L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	42.85	6.30	Mepilex 294100 [MH]

**▪ DRESSING FOAM WITH SILVER**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing foam with silver 12.5 cm x 12.5 cm dressing, 10**

4258D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	267.18	6.30	Allevyn Ag Adhesive 66800078 [SN]

**dressing foam with silver 12.5 cm x 12.5 cm dressing, 10**

4270R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	267.18	6.30	Allevyn Ag Gentle Border 66800462 [SN]

**dressing foam with silver 10 cm x 10 cm dressing, 10**

4255Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	214.69	6.30	Allevyn Ag Adhesive 66800075 [SN]

**dressing foam with silver 10 cm x 10 cm dressing, 10**

4259E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	218.86	6.30	Allevyn Ag Non-Adhesive 66800086 [SN]

**dressing foam with silver 10 cm x 10 cm dressing, 10**

4266M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	214.69	6.30	Allevyn Ag Gentle Border 66800461 [SN]

**dressing foam with silver 7.5 cm x 7.5 cm dressing, 10**

4252T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	145.29	6.30	Allevyn Ag Adhesive 66800073 [SN]

**dressing foam with silver 7.5 cm x 7.5 cm dressing, 10**

4263J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	145.29	6.30	Allevyn Ag Gentle Border 66800460 [SN]

**▪ DRESSING GAUZE ABSORBENT****dressing gauze absorbent 10 cm x 10 cm pad, 100**

4708T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	32.42	6.30	Handy 71117-06 [BV]

**dressing gauze absorbent 5 cm x 5 cm pad, 100**

4707R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.69	6.30	Handy 71117-05 [BV]

**▪ DRESSING GAUZE EYE****dressing gauze eye pad, 12 pads**

4768Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.66	6.30	Curity 4112 [KE]

**▪ DRESSING GAUZE PARAFFIN**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler

cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

#### 4759L dressing gauze paraffin 10 cm x 10 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	25.50	6.30	Jelonet 7404 [SN]

#### ▪ DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

#### 4845B dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	2	..	31.72	6.30	Bactigras 7457 [SN]

#### ▪ DRESSING HYDROACTIVE DEBRIDEMENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

#### DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	82.42	6.30	TenderWet 24 Active 609210 [HR]

#### DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	84.28	6.30	TenderWet Active Cavity 609272 [HR]

#### DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	110.02	6.30	TenderWet 24 Active 609213 [HR]

#### ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

#### dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	55.07	6.30	CombiDERM 651031 [CC]

#### dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	128.74	6.30	Tielle MTL103 [KI]

#### dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	70.45	6.30	CombiDERM 651027 [CC]

#### dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	106.38	6.30	Tielle MTL101E [KI]

#### ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm waterproof pad, 10**

4929K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	93.39	6.30	Biatain Adhesive 3420 [CT]

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm waterproof pad, 10**

4927H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	85.19	6.30	Biatain Non-adhesive 3410 [CT]

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm waterproof pad, 5**

4928J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	83.84	6.30	Biatain Non-adhesive 3413 [CT]

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm waterproof pad, 5**

4930L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	90.54	6.30	Biatain Adhesive 3423 [CT]

**▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10**

4905E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	66.34	6.30	Allevyn Thin 66047576 [SN]

**dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5**

4906F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*117.85	6.30	Allevyn Thin 66047578 [SN]

**▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5**

4886E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*92.49	6.30	Cutinova Hydro 66047443 [SN]

**dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10**

4885D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	56.44	6.30	Cutinova Hydro 66047441 [SN]

**▪ DRESSING HYDROCOLLOID CAVITY WOUND**

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**dressing hydrocolloid cavity wound paste, 30 g**

4896Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*137.15	6.30	DuoDERM Paste H7930 [CC]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

4907G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	70.45	6.30	DuoDERM Extra Thin H7955 [CC]

### ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

#### dressing hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10

4888G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	41.89	6.30	Comfeel Plus Transparent 3530 [CT]

#### dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4924E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	68.69	6.30	Comfeel Plus Transparent 3533 [CT]

#### dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10

4889H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	82.09	6.30	Comfeel Plus Transparent 3536 [CT]

### ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

#### dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4947J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	48.32	6.30	Hydrocoll Thin 900758 [HR]

### ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

#### dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5

4920Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*209.61	6.30	DuoDERM CGF H7662 [CC]

#### dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5

4897R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*79.25	6.30	DuoDERM CGF H7660 [CC]

### ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

#### dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10

4921B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	93.46	6.30	Replicare Ultra 66000434 [SN]

### ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

#### dressing hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10

4946H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	86.99	6.30	Hydrocoll 900936 [HR]

**dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10**

4945G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	48.32	6.30	Hydrocoll 900744 [HR]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydrocolloid superficial wound moderate exudate 10cm (round) dressing, 1**

4679G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*59.45	6.30	Comfeel Plus Pressure Relieving 3353 [CT]

**DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1**

4923D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	79.80	6.30	Comfeel Plus Ulcer Dressing 3110 [CT]

**dressing hydrocolloid superficial wound moderate exudate 7cm (butterfly shape) dressing, 1**

4678F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*55.35	6.30	Comfeel Plus Pressure Relieving 3350 [CT]

**▪ DRESSING HYDROFIBRE ALTERNATE TO ALGINATES****dressing hydrofibre alternate to alginates 12.5 cm x 12.5 cm dressing, 10**

10832D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	116.73	6.30	Aquacel Foam Adhesive [CC]

**dressing hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g**

4698G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	81.35	6.30	Aquacel 403770 [CC]

**dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10**

10837J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	120.20	6.30	Aquacel Foam Non-Adhesive [CC]

**dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10**

2797F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	97.05	6.30	Aquacel Extra 420672 [CC]

**dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5**

2803M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*195.51	6.30	Aquacel Extra 420673 [CC]

**▪ DRESSING HYDROFIBRE GELLING FIBRE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydrofibre gelling fibre 2 cm x 45 cm rope, 5**

2462N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	87.24	6.30	Durafiber 66800563 [SN]

**dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5**

2445Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡2	1	..	*211.59	6.30	Durafiber 66800561 [SN]

**dressing hydrofibre gelling fibre 10 cm x 10 cm dressing, 10**

2486W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	103.62	6.30	Durafiber 66800560 [SN]

## ▪ DRESSING HYDROFIBRE WITH SILVER

### Authority required

Wounds

### Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressings hydrofibre with silver 2 cm x 45 cm rope, 5

10105W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	211.81	6.30	Aquacel Ag 403771 [CC]

### dressings hydrofibre with silver 10 cm x 10 cm dressing, 10

10097K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	250.75	6.30	Aquacel Ag 403708 [CC]

### dressings hydrofibre with silver 15 cm x 15 cm dressing, 5

10098L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	268.39	6.30	Aquacel Ag 403710 [CC]

## ▪ DRESSING HYDROGEL

### dressings hydrogel 10 cm x 10 cm dressing, 20

2471C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	108.93	6.30	Sorbact Absorption Dressing S98222 [QL]

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

### dressings hydrogel amorphous gel, 50 g

4914P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*34.30	6.30	Solugel 10336 [JJ]

### dressings hydrogel amorphous gel, 3 x 30 g

4913N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*93.52	6.30	DuoDERM Gel H7987 [CC]

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### dressings hydrogel amorphous gel, 10 x 15 g

4912M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	63.87	6.30	DuoDERM Gel H7990 [CC]
			..	70.79	6.30	Comfeel Purilon Gel 3900 [CT]

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressings hydrogel amorphous gel, 50 g

4599C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*34.75	6.30	SoloSite Gel 36361338 [SN]

## VARIOUS

### dressing hydrogel amorphous gel, 25 g

4894N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*73.31	6.30	Intrasite Gel 7313 [SN]

### ▪ DRESSING HYDROGEL FOAM

#### dressing hydrogel foam 10 cm x 10 cm dressing, 10

2533H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	77.48	6.30	Sorbact Foam Dressing S98310 [QL]

### ▪ DRESSING HYDROGEL RIBBON

#### dressing hydrogel ribbon 1 cm x 50 cm dressing, 20

2512F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	112.43	6.30	Sorbact Ribbon Gauze S98118 [QL]

#### dressing hydrogel ribbon 5 cm x 200 cm dressing, 10

2529D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	108.93	6.30	Sorbact Ribbon Gauze S98120 [QL]

### ▪ DRESSING HYDROGEL SHEET

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

#### dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5

4911L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*80.89	6.30	Nu-Gel 2497 [KI]

### ▪ DRESSING HYDROGEL SHEET

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

#### dressing hydrogel sheet 10 cm x 10 cm dressing, 5

4806Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*53.45	6.30	Hydrosorb 900854 [HR]

### ▪ DRESSING NON ADHERENT

**Note** Moliney Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Moliney Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

#### DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1

4243H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	63.09	6.30	Mepitel 290510 [MH]

#### DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1

4244J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	103.09	6.30	Mepitel 290710 [MH]

### ▪ DRESSING NON ADHERENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

#### dressing non adherent 7.5 cm x 10 cm dressing, 10

4944F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.76	6.30	Atrauman 499513 [HR]

## ▪ DRESSING NON ADHERENT

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressings non adherent 10 cm x 10 cm dressing, 5

4862X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*28.93	6.30	Cutilin Non-Stick Wound Pad 36361375 [SN]

### dressings non adherent 10 cm x 10 cm dressing, 10

4861W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	39.21	6.30	Melolin 66974933 [SN]

### dressings non adherent 5 cm x 5 cm dressing, 5

4819P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*19.89	6.30	Cutilin Non-Stick Wound Pad 36361374 [SN]

### dressings non adherent 5 cm x 5 cm dressing, 5

4860T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*21.13	6.30	Melolin 36361357 [SN]

## ▪ DRESSING TULLE NON GAUZE PARAFFIN

### dressings tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1

4909J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*19.15	6.30	Adaptic 2012 [KI]

## ▪ DRESSING WITH SILVER

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

#### Authority required

Wounds

#### Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressings with silver 12.5 cm x 12.5 cm hydroactive dressing, 5

4647N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	179.15	6.30	Biatain Ag 9632 [CT]

### dressings with silver 10 cm x 10 cm hydroactive dressing, 5

4646M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	165.14	6.30	Biatain Ag 9622 [CT]

## ▪ DRESSING WITH SILVER

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

#### Authority required

Wounds

#### Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressings with silver 10 cm x 10 cm tulle dressing, 3

4648P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	43.95	6.30	Atrauman Ag 499572 [HR]

## GAUZE AND COTTON TISSUE COMBINE ROLL

### gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack

4767X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.78	6.30	BSN 2902165 [BV]

### gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack

4761N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.47	6.30	JJ 12010 [JJ]

## POVIDONE-IODINE

### povidone-iodine 9.5 cm x 9.5 cm dressing, 25

10847X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	77.64	6.30	Inadine [KI]

## SODIUM CHLORIDE + HYPOCHLOROUS ACID + SODIUM HYPOCHLORITE

### sodium chloride 0.022% + hypochlorous acid 0.004% + sodium hypochlorite 0.004% irrigation solution, 250 mL

11134B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	30.44	6.30	Microdacyn [TF]

## TAPE NON WOVEN RETENTION POLYACRYLATE

### tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll

4915Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.70	6.30	Medipore 2961 [MM]

## TAPE NON WOVEN RETENTION POLYACRYLATE

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### tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll

4917T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.11	6.30	Mefix 310250 [MH]

## TAPE PLASTER ADHESIVE ELASTIC

### tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll

4782Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	27.24	6.30	Leukoplast 01073-00 [BV]

### tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll

4781P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	23.56	6.30	Leukoplast 01072-00 [BV]

### tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll

4780N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.62	6.30	Leukoplast 01071-00 [BV]

## TAPE PLASTER ADHESIVE HYPOALLERGENIC

### tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4783R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.03	6.30	Leukopor 2471 [BV]

### tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4785W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.32	6.30	Leukosilk 1021 [BV]

### tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll

4849F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.12	6.30	Nexcare Gentle Paper First Aid Tape 789 [MM]

**tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll**

4788B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	20.47	6.30	Leukoflex 1124 [BV]	

**tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll**

4789C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	21.79	6.30	Leukosilk 1024 [BV]	

**tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll**

4790D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	20.96	6.30	Leukopor 2474 [BV]	

**tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll**

4787Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	17.97	6.30	Leukosilk 1022 [BV]	

**tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll**

4794H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	17.44	6.30	Leukopor 2472 [BV]	

**tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll**

4848E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	15.12	6.30	Nexcare Durable Cloth First Aid Tape 799 [MM]	

**■ TAPE PLASTER ADHESIVE WITH SILICONE**

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**tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll**

4240E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	24.09	6.30	Mepitac 298400 [MH]	

**tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll**

4239D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	24.09	6.30	Mepitac 298300 [MH]	

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# Extemporaneously Prepared Benefits

# Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Acacia Mucilage (by weight)	APF 15	0.02	0.12	0.96	8.49
Acacia, powdered	BP	0.03	0.22	1.79	15.91
Acetic Acid (33 per cent)	BP	0.01	0.06	0.46	4.07
Acetic Acid (6 per cent)	BP	0.01	0.02	0.15	1.31
Acetic Acid Glacial BP	BP	0.02	0.14	1.09	9.69
Acetone (use as additive only)	BP	0.03	0.20	1.63	14.50
Alum	BP	0.01	0.07	0.59	5.25
Aluminium Acetate Solution	BP	0.02	0.17	1.38	12.27
Anise Oil BP	BP	0.18	1.44	11.52	102.44
Anise Water Concentrated 1 in 40	BP	0.01	0.07	0.57	5.03
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.03	0.24	2.10
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.37	2.99	23.94	212.76
Aspirin	BP	0.14	1.15	9.22	81.94
Belladonna Tincture	BP	0.10	0.81	6.44	57.28
Benzocaine	BP	0.12	0.97	7.76	68.94
Benzoic Acid	BP	0.06	0.48	3.80	33.80
Benzoic Acid Compound Ointment	APF	0.02	0.16	1.26	11.22
Benzoic Acid Solution	BP	0.02	0.14	1.09	9.73
Benzooin Compound Tincture	BP	0.05	0.43	3.47	30.81
Boric Acid (use as additive only)	BP	0.02	0.19	1.55	13.79
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.02	0.14	1.09	9.67
Calcium Hydroxide	BP	0.10	0.83	6.64	59.00
Calcium Hydroxide Solution	BP	0.01	0.02	0.17	1.52
Castor Oil (use as additive only)	BP	0.02	0.18	1.41	12.50
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.04	0.28	2.48
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.02	0.17	1.37	12.21
Chlorhexidine Acetate (use as additive only)	BP	0.63	5.03	40.21	357.42
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.03	0.24	1.95	17.36
Chloroform (use as additive only)	BP	0.09	0.72	5.77	51.29
Chloroform Spirit	BP	0.01	0.08	0.67	5.94
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.11	0.84	7.45
Citric Acid Monohydrate	BP	0.04	0.29	2.28	20.25
Coal Tar	BP	0.28	2.21	17.70	157.34
Coal Tar Solution	BP	0.02	0.16	1.25	11.15
Cocaine Hydrochloride	BP	5.41	43.26	346.09	3076.38
Coconut Oil	BP	0.01	0.05	0.42	3.73
Codeine Linctus	APF	0.01	0.10	0.79	7.03
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	3.82	30.58	244.67	2174.84
Collodion Flexible	BP	0.19	1.55	12.37	109.92
Dithranol	BP	4.31	34.48	275.84	2451.94
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.09	0.71	6.27
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	2.05	16.43	131.45	1168.43

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.04	0.28	2.45
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.04	0.35	3.10
Ether Solvent (use as additive only)	BP	0.25	1.97	15.73	139.82
Eucalyptus Oil (use as additive only)	BP	0.02	0.18	1.42	12.64
Ferrous Sulfate	BP	0.04	0.29	2.32	20.59
Formaldehyde Solution	BP	0.07	0.53	4.26	37.86
Gentian Alkaline Mixture	APF	0.01	0.09	0.68	6.00
Glycerol	BP	0.02	0.12	0.98	8.72
Honey Purified (use as additive only)	BP 1993	0.01	0.03	0.27	2.44
Hydroxybenzoate Compound Solution	APF	0.07	0.59	4.73	42.08
Iodine	BP	0.37	2.98	23.85	211.97
Iodine Alcoholic Solution	BP	0.04	0.28	2.26	20.11
Iodine Aqueous Oral Solution	BP	0.03	0.26	2.11	18.72
Kaolin Mixture	BPC 1968	0.03	0.21	1.71	15.19
Kaolin and Opium Mixture	APF 14	0.01	0.10	0.82	7.27
Lactic Acid	BP	0.36	2.87	22.94	203.95
Lavender Spike Oil	BPC 1968	0.13	1.04	8.32	73.91
Liquorice Liquid Extract	BP	0.03	0.23	1.84	16.37
Magnesium Carbonate Light	BP	0.05	0.37	2.92	25.99
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.03	0.24	2.10
Magnesium Trisilicate	BP	0.05	0.36	2.91	25.82
Menthol, Racemic or Levomenthol	BP	0.25	2.02	16.19	143.87
Methyl Hydroxybenzoate	BP	0.41	3.28	26.22	233.03
Methyl Hydroxybenzoate Solution	APF	0.04	0.35	2.80	24.87
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.01	0.08	0.73
Olive Oil (use as additive only)	BP	0.02	0.14	1.08	9.62
Paraffin Hard	BP	0.05	0.41	3.29	29.28
Paraffin Light Liquid	BP	0.02	0.17	1.39	12.32
Paraffin Liquid (use as additive only)	BP	0.01	0.06	0.51	4.56
Paraffin Soft White	BP	0.01	0.05	0.42	3.71
Paraffin Soft Yellow	BP	0.01	0.05	0.42	3.75
Peppermint Oil (use as additive only)	BP	0.07	0.57	4.55	40.44
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.04	0.34	2.72	24.17
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	9.37	74.92	599.36	5327.61
Phenol Liquefied (not available for ear drops)	BP	0.13	1.02	8.17	72.64
Podophyllum Resin	BP	3.78	30.25	242.03	2151.34
Potassium Citrate	BP	0.02	0.19	1.53	13.64
Potassium Iodide	BP	0.14	1.11	8.88	78.94
Potassium Permanganate	BP	0.04	0.31	2.44	21.65
Propyl Hydroxybenzoate	BP	0.42	3.35	26.78	238.01
Propylene Glycol	BP	0.02	0.12	0.95	8.48
Red Syrup	APF 15	0.02	0.13	1.04	9.23
Resorcinol	BP	0.42	3.32	26.54	235.88
Salicylic Acid	BP	0.05	0.40	3.18	28.25
Salicylic Acid Ointment	APF	0.02	0.17	1.38	12.23
Salicylic Acid Ointment	BP	0.02	0.17	1.38	12.23
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Sodium Bicarbonate	BP	0.04	0.28	2.24	19.91
Sodium Chloride	BP	0.02	0.17	1.34	11.88
Sodium Chloride Solution	BP	0.01	0.01	0.09	0.84
Sodium Citrate	BP	0.04	0.28	2.23	19.81
Sodium Thiosulfate (use as additive only)	BP	0.04	0.34	2.74	24.37
Starch	BP	0.02	0.19	1.55	13.79
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.15	1.21	10.75
Sulfur Precipitated	BP 1980	0.03	0.23	1.86	16.49
Syrup	BP	0.01	0.05	0.42	3.71
Talc Purified, sterilised	BP	0.06	0.46	3.71	32.94
Thymol	BP	0.46	3.71	29.66	263.61
Thymol Compound Mouth Wash	APF 15	0.01	0.11	0.89	7.91

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Tragacanth Compound Powder	BP 1980	0.07	0.57	4.58	40.73
Tragacanth Mucilage	APF 13	0.01	0.07	0.58	5.14
Tragacanth Mucilage	BPC 1973	0.01	0.06	0.51	4.56
Tragacanth, powdered	BP	0.36	2.84	22.72	201.94
Trichloroacetic Acid	BP 1980	0.33	2.65	21.23	188.68
Triethanolamine	BP	0.12	0.96	7.68	68.28
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP				
Water Purified	BP	0.01	0.01	0.08	0.69
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.17	1.33	11.86
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.19	1.48	13.18
Wool Fat	BP	0.02	0.12	0.97	8.63
Wool Fat Hydrous	BP	0.03	0.25	2.03	18.01
Zinc Compound Paste	BP	0.05	0.40	3.17	28.17
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.01	0.08	0.61	5.39
Zinc Oxide	BP	0.03	0.21	1.66	14.79
Zinc Sulfate	BP	0.04	0.28	2.21	19.63
Zinc and Salicylic Acid Paste	BP	0.04	0.32	2.53	22.47

# Container Prices

Type	Container	Price \$
Dispensing Bottles	25mL	0.64
Dispensing Bottles	50mL	0.53
Dispensing Bottles	100mL	0.87
Dispensing Bottles	200mL	1.03
Dispensing Bottles	500mL	1.28
Poison Bottles	25mL	0.67
Poison Bottles	50mL	0.54
Poison Bottles	100mL	0.79
Poison Bottles	200mL	1.02
Poison Bottles	500mL	1.69
Dropper Containers (Glass)	15mL	1.21
Dropper Containers (Polythene)	15mL	0.98
	150ml	0.83
Screw Cap Jars	25g	0.90
Screw Cap Jars	50g	0.96
Screw Cap Jars	100g	0.99
Screw Cap Jars	200g	0.85
Screw Cap Jars	500g	2.19
	25ml	0.41

# Standard Formula Preparations

Code	Item	Reference	DPMQ \$	MRVSN \$
	<b>Creams</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7502W	Salicylic Acid and Sulfur Aqueous	APF	13.47	15.04
	<b>Dusting Powders</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7458M	Zinc, Starch and Talc	APF 15 & BPC 1973	36.61	38.18
	<b>Ear Drops</b>			
	<b>(Maximum Quantity 15 ml and 2 Repeats)</b>			
7643G	Aluminium Acetate	BP	12.24	13.81
7642F	Aluminium Acetate	APF	11.47	13.04
7314Y	Sodium Bicarbonate	APF & BP	11.01	12.58
7313X	Spirit	APF	10.44	12.01
	<b>Inhalations</b>			
	<b>(Maximum Quantity 50 ml and 1 Repeat)</b>			
7484X	Benzoin and Menthol	APF	29.08	30.65
7308P	Menthol	APF	13.13	14.70
7310R	Menthol and Eucalyptus	BP1980	14.27	15.84
	<b>Linctuses containing Codeine Phosphate</b>			
	<b>(Maximum Quantity 100 ml and 0 Repeat)</b>			
7530H	Codeine	APF	17.09	18.66
	<b>Lotions</b>			
	<b>(Maximum Quantity 200 ml and 2 Repeats)</b>			
7709R	Aluminium Acetate Aqueous	APF	12.90	14.47
	<b>Mixtures, Other</b>			
	<b>(Maximum Quantity 200 ml and 4 Repeats)</b>			
7604F	Gentian Alkaline	APF	22.22	23.79
7348R	Kaolin	BPC 1968	40.59	38.80
7301G	Kaolin and Opium	APF 14	24.76	26.33
7342K	Magnesium Trisilicate	BPC 1968	21.34	22.91
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	27.63	29.20
	<b>Mouth Washes</b>			
	<b>(Maximum Quantity 200 ml and 1 Repeat)</b>			
7457L	Thymol Compound	APF 15	26.03	27.60
	<b>Ointments, Waxes</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7914M	Benzoic Acid Compound	APF & BP	21.40	22.97
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	19.85	21.42
7926E	Salicylic Acid	APF	22.41	23.98
7928G	Salicylic Acid (extemporaneous formula)	BP	22.41	23.98
	<b>Paints</b>			
	<b>(Maximum Quantity 25 ml and 1 Repeat)</b>			
7567G	Podophyllin Compound	APF 16 & BP	131.97	38.80
7568H	Salicylic Acid	APF	41.77	38.80
	<b>Pastes, Other</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7558T	Zinc	APF & BP	38.35	38.80
	<b>Powders for Internal Use</b>			
	<b>(Maximum Quantity 100 g and 2 Repeats)</b>			
7545D	Magnesium Trisilicate	BP	35.86	37.43

# Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 ml	2
19B	Eye Drops containing Cocaine Hydrochloride	15 ml	..
22E	Eye Drops, Other	15 ml	5
23F	Eye Lotions	200 ml	2
29M	Inhalations	50 ml	1
64J	Linctuses containing Codeine Phosphate	100 ml	..
34T	Linctuses, Other	100 ml	2
39C	Lotions	200 ml	2
65K	Mixtures containing Codeine Phosphate	200 ml	..
66L	Mixtures for Children containing Codeine Phosphate	100 ml	..
41E	Mixtures for Children, Other	100 ml	4
40D	Mixtures, Other	200 ml	4
30N	Mouth Washes	200 ml	1
42F	Nasal Instillations	15 ml	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 ml	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 ml	2

# Index of Manufacturers' Code

<b>Code</b>	<b>Manufacturer</b>	<b>Code</b>	<b>Manufacturer</b>
<b>AB</b>	Abbott Australasia Pty Ltd	<b>FP</b>	Ferring Pharmaceuticals Pty Limited
<b>AE</b>	AFT Pharmaceuticals Pty Ltd	<b>FR</b>	Merck Sharp & Dohme (Australia) Pty Ltd
<b>AF</b>	Alphapharm Pty Ltd	<b>FX</b>	Finox Biotech Australia
<b>AG</b>	Allergan Australia Pty Limited	<b>FZ</b>	Pfizer Australia Pty Ltd
<b>AL</b>	Alphapharm Pty Ltd	<b>GA</b>	Galderma Australia Pty Ltd
<b>AN</b>	Amgen Australia Pty Limited	<b>GC</b>	GlaxoSmithKline Australia Pty Ltd
<b>AP</b>	AstraZeneca Pty Ltd	<b>GH</b>	Amdipharm Mercury (Australia) Pty Limited
<b>AS</b>	Aspen Pharmacare Australia Pty Limited	<b>GI</b>	Gilead Sciences Pty Limited
<b>AT</b>	Actelion Pharmaceuticals Australia Pty Ltd	<b>GK</b>	GlaxoSmithKline Australia Pty Ltd
<b>AV</b>	sanofi-aventis Australia Pty Ltd	<b>GN</b>	Actavis Pty Ltd
<b>BB</b>	Blackmores Limited	<b>GO</b>	BGP Products Pty Ltd
<b>BD</b>	Biogen Australia Pty Ltd	<b>GQ</b>	Generic Health Pty Ltd
<b>BE</b>	Beiersdorf Australia Ltd	<b>GT</b>	BGP Products Pty Ltd
<b>BG</b>	Sandoz Pty Ltd	<b>GV</b>	Amgen Australia Pty Limited
<b>BI</b>	Biotech Pharmaceuticals Pty Ltd	<b>GX</b>	Apotex Pty Ltd
<b>BN</b>	Bayer Australia Ltd	<b>GZ</b>	sanofi-aventis Australia Pty Ltd
<b>BQ</b>	Bristol-Myers Squibb Australia Pty Ltd	<b>HB</b>	Besins Healthcare Australia Pty Ltd
<b>BR</b>	B. Braun Australia Pty Ltd	<b>HM</b>	Meda Pharmaceuticals Pty Ltd
<b>BV</b>	BSN medical (Aust.) Pty Ltd	<b>HQ</b>	Generic Health Pty Ltd
<b>BX</b>	Baxter Healthcare Pty Limited	<b>HR</b>	Paul Hartmann Pty Ltd
<b>BY</b>	Boehringer Ingelheim Pty Ltd	<b>HX</b>	Sandoz Pty Ltd
<b>BZ</b>	Boucher & Muir Pty Ltd	<b>IA</b>	iNova Pharmaceuticals (Australia) Pty Limited
<b>CC</b>	ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd	<b>IB</b>	Apotex Pty Ltd
<b>CF</b>	CNS Pharma Pty Ltd	<b>IO</b>	BioMarin Pharmaceutical Australia Pty Ltd
<b>CH</b>	Apotex Pty Ltd	<b>IR</b>	Indivior Pty Ltd
<b>CJ</b>	Celgene Pty Limited	<b>IS</b>	Ipsen Pty Ltd
<b>CR</b>	Pharmacor Pty Limited	<b>IV</b>	iNova Pharmaceuticals (Australia) Pty Limited
<b>CS</b>	Seqirus (Australia) Pty Ltd	<b>IX</b>	Clinect Pty Ltd
<b>CT</b>	Coloplast Pty Ltd	<b>IY</b>	Clinect Pty Ltd
<b>CU</b>	Care Pharmaceuticals Pty Limited	<b>JC</b>	Janssen-Cilag Pty Ltd
<b>CX</b>	Contact Lens Centre Australia Limited	<b>JJ</b>	Johnson & Johnson Medical Pty Ltd
<b>DE</b>	Stallergenes Australia Pty Ltd	<b>JO</b>	Juno Pharmaceuticals Pty Ltd
<b>DJ</b>	De Fries Industries Pty Ltd	<b>JT</b>	Johnson & Johnson Pacific Pty Limited
<b>DO</b>	Aurobindo Pharma (Australia) Pty Limited	<b>JU</b>	Juno Pharmaceuticals Pty Ltd
<b>DQ</b>	Church & Dwight (Australia) Pty Ltd	<b>KE</b>	Kendall Australasia Pty Ltd
<b>DV</b>	Medical Developments International Limited	<b>KI</b>	KCI Medical Australia Pty Ltd
<b>DZ</b>	Medsurge Healthcare Pty Ltd	<b>KP</b>	Eli Lilly Australia Pty Ltd
<b>EA</b>	Amneal Pharmaceuticals Pty Ltd	<b>KY</b>	Key Pharmaceuticals Pty Ltd
<b>ED</b>	Amneal Pharmaceuticals Pty Ltd	<b>LI</b>	Luminarie Pty Ltd
<b>EF</b>	Amneal Pharmaceuticals Pty Ltd	<b>LL</b>	Astellas Pharma Australia Pty Ltd
<b>EI</b>	Eisai Australia Pty Ltd	<b>LM</b>	Link Medical Products Pty Ltd
<b>EL</b>	Eli Lilly Australia Pty Ltd	<b>LN</b>	Aspen Pharmacare Australia Pty Limited
<b>EO</b>	Ego Pharmaceuticals Proprietary Limited	<b>LO</b>	Leo Pharma Pty Ltd
<b>ER</b>	Eris Pharmaceuticals (Australia) Pty Ltd	<b>LQ</b>	Astellas Pharma Australia Pty Ltd
<b>EU</b>	Emerge Health Pty Ltd	<b>LR</b>	Cipla Australia Pty Ltd
<b>EZ</b>	Merz Australia Pty Ltd	<b>LS</b>	Astellas Pharma Australia Pty Ltd
<b>FB</b>	Pierre Fabre Medicament Australia Pty Ltd	<b>LU</b>	Lundbeck Australia Pty Ltd
<b>FI</b>	Boehringer Ingelheim Pty Ltd	<b>LX</b>	Lawley Pharmaceuticals Pty Ltd
<b>FK</b>	A. Menarini Australia Pty Limited	<b>LY</b>	Eli Lilly Australia Pty Ltd
<b>FM</b>	Fawns and McAllan Proprietary Limited	<b>MF</b>	Mundipharma Pty Limited
<b>FN</b>	Fresenius Medical Care Australia Pty Ltd	<b>MH</b>	Molnlycke Health Care Pty Ltd
<b>FO</b>	For Benefit Medicines Pty Ltd	<b>MK</b>	Merck Sharp & Dohme (Australia) Pty Ltd
		<b>MM</b>	3M Pharmaceuticals Australia Pty Ltd

<b>Code</b>	<b>Manufacturer</b>	<b>Code</b>	<b>Manufacturer</b>
<b>MT</b>	Mentholatum Australasia Pty Ltd	<b>VF</b>	Vitaflo Australia Pty Limited
<b>MW</b>	Biomed Aust Pty Limited	<b>VI</b>	ViiV Healthcare Pty Ltd
<b>NE</b>	Norgine Pty Limited	<b>VL</b>	Vifor Pharma Pty Limited
<b>NF</b>	Novo Nordisk Pharmaceuticals Pty Limited	<b>VR</b>	Vertex Pharmaceuticals (Australia) Pty Ltd
<b>NI</b>	Novo Nordisk Pharmaceuticals Pty Limited	<b>VZ</b>	Sanofi-aventis Healthcare Pty Ltd
<b>NM</b>	Novartis Pharmaceuticals Australia Pty Limited	<b>WA</b>	sanofi-aventis Australia Pty Ltd
<b>NO</b>	Novo Nordisk Pharmaceuticals Pty Limited	<b>XA</b>	Pharmaxis Ltd
<b>NQ</b>	Takeda Pharmaceuticals Australia Pty Ltd	<b>XC</b>	Southern Cross Pharma Pty Ltd
<b>NT</b>	Nestle Australia Ltd	<b>XH</b>	MS Health Pty Ltd
<b>NU</b>	Nutricia Australia Pty Limited	<b>XI</b>	Alexion Pharmaceuticals Australasia Pty Ltd
<b>NV</b>	Novartis Pharmaceuticals Australia Pty Limited	<b>XM</b>	The Medicines Company (Australia) Pty Limited
<b>OA</b>	Orphan Australia Pty Ltd	<b>YC</b>	Cipla Australia Pty Ltd
<b>OB</b>	Oral B Laboratories Pty Ltd	<b>YN</b>	Mayne Pharma International Pty Ltd
<b>OC</b>	Accord Healthcare Pty Ltd	<b>YT</b>	Mayne Products Pty Ltd
<b>OD</b>	Accord Healthcare Pty Ltd	<b>ZA</b>	AstraZeneca Pty Ltd
<b>OE</b>	Omegapharm Pty Ltd	<b>ZI</b>	Shire Australia Pty Limited
<b>OH</b>	Orpharma Pty Ltd	<b>ZP</b>	Medis Pharma Pty Ltd
<b>OL</b>	Owen Laboratories Division of Galderma Australia Pty Ltd	<b>ZX</b>	Zenex Pharmaceuticals Pty Ltd
<b>OM</b>	Colgate Oral Care		
<b>ON</b>	Orion Laboratories Pty Ltd		
<b>OS</b>	Otsuka Australia Pharmaceutical Pty Ltd		
<b>OW</b>	Arrow Pharma Pty Ltd		
<b>PB</b>	Pharmaco (Australia) Limited		
<b>PE</b>	Allergan Australia Pty Limited		
<b>PF</b>	Pfizer Australia Pty Ltd		
<b>PK</b>	Fresenius Kabi Australia Pty Limited		
<b>PL</b>	The Trustee for Virgo Unit Trust (trading as Phebra)		
<b>PM</b>	Pharmaceutical Manufacturing Company Pty Limited		
<b>PP</b>	Petrus Pharmaceuticals Pty Ltd		
<b>PQ</b>	PMIP Pty Ltd		
<b>PY</b>	Procter & Gamble Pharmaceuticals Australia Pty Ltd		
<b>QA</b>	Aspen Pharma Pty Ltd		
<b>QH</b>	Cortex Health Pty Ltd		
<b>QL</b>	Amcla Pty Limited		
<b>RA</b>	Sun Pharma ANZ Pty Ltd		
<b>RB</b>	Bio Revive Pty Ltd		
<b>RC</b>	Reckitt Benckiser (Australia) Pty Limited		
<b>RF</b>	Arrow Pharma Pty Ltd		
<b>RI</b>	Dr Reddy's Laboratories (Australia) Pty Ltd		
<b>RN</b>	Sun Pharma ANZ Pty Ltd		
<b>RO</b>	Roche Products Pty Ltd		
<b>RW</b>	Arrow Pharma Pty Ltd		
<b>RX</b>	Servier Laboratories (Aust.) Pty Ltd		
<b>RZ</b>	Dr Reddy's Laboratories (Australia) Pty Ltd		
<b>SA</b>	SciGen (Australia) Pty Limited		
<b>SB</b>	Nutricia Australia Pty Limited		
<b>SE</b>	Servier Laboratories (Aust.) Pty Ltd		
<b>SG</b>	Merck Serono Australia Pty Ltd		
<b>SI</b>	Sigma Company Limited		
<b>SN</b>	Smith & Nephew Pty Limited		
<b>SS</b>	SSL Australia Pty Ltd		
<b>SW</b>	sanofi-aventis Australia Pty Ltd		
<b>SY</b>	Bayer Australia Ltd		
<b>SZ</b>	Sandoz Pty Ltd		
<b>TB</b>	Teva Pharma Australia Pty Limited		
<b>TD</b>	STADA Pharmaceuticals Australia Pty Limited		
<b>TF</b>	Te Arai BioFarma Limited		
<b>TK</b>	Takeda Pharmaceuticals Australia Pty Ltd		
<b>TL</b>	Tolmar Australia Pty Ltd		
<b>TM</b>	Technipro Marketing Pty Ltd		
<b>TS</b>	Specialised Therapeutics Australia Pty Ltd		
<b>TW</b>	Apotex Pty Ltd		
<b>TX</b>	Apotex Pty Ltd		
<b>UA</b>	Actavis Pty Ltd		
<b>UC</b>	UCB Australia Proprietary Limited		
<b>UM</b>	Unomedical Pty Ltd		
<b>UN</b>	Unilever Australia Limited		
<b>VE</b>	AbbVie Pty Ltd		

# Generic/Proprietary Index

3TC(VI).....	1325	<i>Actemra Subcutaneous Injection(RO)</i> .....	581, 585
ABACAVIR.....	1323	<i>Actemra(RO)</i> ...	1016, 1017, 1023, 1029, 1033, 1255, 1262, 1267, 1272
ABACAVIR + LAMIVUDINE.....	1330	<i>Actiq(TB)</i> .....	834, 835, 836, 837
ABACAVIR + LAMIVUDINE + ZIDOVUDINE.....	1330	<i>Actisorb Plus MAP105(KI)</i> .....	1679
ABATACEPT.....	357, 360, 931, 1170	<i>Actonel EC Combi D(UA)</i> .....	628, 1665
ABCIXIMAB.....	97	<i>Actonel EC Combi(UA)</i> .....	627, 1664
<i>Abilify Maintena(LU)</i> .....	689	<i>Actonel EC(UA)</i> .....	623, 1663
<i>Abilify(OS)</i> .....	689	<i>Actonel Once-a-Month (UA)</i> .....	623
ABIRATERONE.....	353	<i>Actonel(UA)</i> .....	622, 623, 1663
<i>Abisart HCT 150/12.5(AF)</i> .....	147	<i>Actos(TK)</i> .....	79
<i>Abisart HCT 300/12.5(AF)</i> .....	146	<i>Actrapid Penfill 3 mL(NO)</i> .....	63
<i>Abisart HCT 300/25(AF)</i> .....	147	<i>Actrapid(NO)</i> .....	63
<i>Abisart(AF)</i> .....	142, 143	<i>Acyclo-V 200(AF)</i> .....	273
<i>Abstral(FK)</i> .....	834, 835, 836, 837	<i>Adalat 10(BN)</i> .....	130
<i>Abyraz (AF)</i> .....	689	<i>Adalat 20(BN)</i> .....	130
ACAMPROSATE.....	730	<i>Adalat Oros 20mg(BN)</i> .....	130
ACARBOSE.....	78	<i>Adalat Oros 30(BN)</i> .....	130
<i>Acarbose Mylan(AF)</i> .....	78	<i>Adalat Oros 60(BN)</i> .....	130
<i>Accomin Adult Tonic(PF)</i> .....	1647	ADALIMUMAB375, 377, 379, 382, 385, 386, 387, 390, 394, 397, 402, 404, 406, 409, 413, 417, 422, 424, 429, 432, 436, 957, 1196	
<i>Accupril(PF)</i> .....	135	ADAPALENE + BENZOYL PEROXIDE.....	205
<i>Accuretic 10/12.5mg(PF)</i> .....	139	<i>Adaptic 2012(KI)</i> .....	1693
<i>Accuretic 20/12.5mg(PF)</i> .....	139	<i>Adcirca(LY)</i> .....	904, 1141
ACETAZOLAMIDE.....	756	<i>add-ins(SB)</i> .....	815
<i>Acetec(AL)</i> .....	132	<i>Addos XR 30(RW)</i> .....	130
ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID.....	1658	<i>Addos XR 60(RW)</i> .....	130
ACICLOVIR.....		<i>Adefin 10(AF)</i> .....	130
. ANTIINFECTIVES FOR SYSTEMIC USE.....	273	<i>Adefin 20(AF)</i> .....	130
. SENSORY ORGANS.....	751	<i>Adefin XL 30 (AF)</i> .....	130
<i>Aciclovir 200(CR)</i> .....	273	<i>Adefin XL 60 (AF)</i> .....	130
<i>Aciclovir 800(CR)</i> .....	273	ADEFOVIR DIPIVOXIL.....	1323
<i>Aciclovir AN (ED)</i> .....	273	<i>Adempas(BN)</i> .....	886, 887, 894, 1123, 1124, 1131, 1132
<i>Aciclovir GH(GQ)</i> .....	273	<i>Adenuric(FK)</i> .....	620
<i>Aciclovir Sandoz (HX)</i> .....	273	<i>Adesan HCT 16/12.5(AF)</i> .....	145
<i>Aciclovir Sandoz(HX)</i> .....	273	<i>Adesan HCT 32/12.5(AF)</i> .....	145
<i>Aci-Jel(CU)</i> .....	1658	<i>Adesan HCT 32/25(AF)</i> .....	146
<i>Acimax Tablets(AL)</i> .....	38, 39	<i>Adesan(AF)</i> .....	141, 142
ACITRETIN.....	193	ADRENALINE.....	
<i>Aclasta(HX)</i> .....	623, 624	. CARDIOVASCULAR SYSTEM.....	115
ACLIDINIUM.....	744	. Prescriber Bag.....	23
ACLIDINIUM + EFORMOTEROL.....	742	. RESPIRATORY SYSTEM.....	746
<i>Aclor 125(QA)</i> .....	249	<i>ADT Booster(CS)</i> .....	24, 283
<i>Aclor 250(QA)</i> .....	249	<i>ADVAGRAF XL(LQ)</i> .....	607, 1039, 1277
<i>Acpio 15(RF)</i> .....	79	<i>Advantan(BN)</i> .....	199, 200, 201
<i>Acpio 30(RF)</i> .....	79	<i>Aeron 250(QA)</i> .....	745
<i>Acpio 45(RF)</i> .....	79	<i>Aeron 500(QA)</i> .....	745
<i>Acquin Aspen 10(RW)</i> .....	135	<i>Afinitor(NV)</i> .....	302, 303, 304
<i>Acquin Aspen 20 (RW)</i> .....	135	AFLIBERCEPT.....	763, 764
<i>Acquin Aspen 5 (RW)</i> .....	135	<i>Aggrastat(AS)</i> .....	102
ACQUIN(RF).....	135	<i>Airomir Autohaler(IA)</i> .....	737
<i>Acris Combi(AF)</i> .....	627, 1665	<i>Akamin 50(AF)</i> .....	236
<i>Acris Once-a-Month(AF)</i> .....	623	<i>Akineton(GH)</i> .....	670
<i>Acris Once-a-Week(AF)</i> .....	623, 1663		
<i>Actaze (RW)</i> .....	79		

<i>Akynzeo(MF)</i> .....	44	<i>AlphaClav Duo(AF)</i> .....	244, 245
<i>Albalon Liquifilm(AG)</i> .....	1672	<i>Alphagan P 1.5(AG)</i> .....	755
<i>Albalon-A(AG)</i> .....	1672	<i>Alphagan(AG)</i> .....	755
ALBENDAZOLE.....	734	<i>Alphamox 125(AF)</i> .....	237, 238
<i>Albey Bee Venom(DE)</i> .....	783	<i>Alphamox 250(AF)</i> .....	237, 238
<i>Albey Paper Wasp Venom(DE)</i> .....	783	<i>Alphamox 500(AF)</i> .....	237
<i>Albey Yellow Jacket Venom(DE)</i> .....	783	<i>Alphapress 25(AF)</i> .....	120
<i>Aldactone(PF)</i> .....	122	<i>Alphapress 50(AF)</i> .....	119
<i>Aldara Pump(IA)</i> .....	207, 1657	<i>Alprax 0.25(QA)</i> .....	697
<i>Aldara(IA)</i> .....	207, 1656, 1657	<i>Alprax 0.5(QA)</i> .....	696
<i>Aldiq(QA)</i> .....	207, 1656, 1657	<i>Alprax 1(QA)</i> .....	696
<i>Aldomet(AS)</i> .....	118	ALPRAZOLAM .....	696
ALEMTUZUMAB.....	936, 937, 1175	<i>Alprim(AF)</i> .....	252, 253
<i>Alendro Once Weekly (RW)</i> .....	621	ALPROSTADIL.....	1658
<i>Alendrobell 70mg(GQ)</i> .....	621	ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE .....	1643
ALENDRONATE.....	621	<i>Alvesco 160(AP)</i> .....	744
ALENDRONATE + COLECALCIFEROL.....	624, 625, 1663	<i>Alvesco 80(AP)</i> .....	744
ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE.....	626, 1664	<i>Alzene(AF)</i> .....	1671
<i>Alendronate AN (EA)</i> .....	621	AMANTADINE.....	673
<i>Alendronate Plus D3 Sandoz (SZ)</i> .....	625, 626	<i>Amaryl(SW)</i> .....	66, 67
<i>Alendronate plus D3-DRLA(RZ)</i> .....	625, 626, 1663, 1664	AMBRISENTAN .....	853, 1091
<i>Alendronate Sandoz(SZ)</i> .....	621	<i>AMCLAVOX DUO 500/125 (RW)</i> .....	244, 245
<i>Alepam 15(AF)</i> .....	698, 699, 840	<i>AMCLAVOX DUO FORTE 875/125 (RW)</i> .....	243, 244
<i>Alepam 30(AF)</i> .....	698, 699, 840	<i>Amdipharm Mercury (Australia) Pty Limited(GH)</i> .CARDIOVASCULAR SYSTEM.....	123
<i>Alfamino Junior(NT)</i> .....	805, 806	.GENITO URINARY SYSTEM AND SEX HORMONES .....	223
<i>Alfamino(NT)</i> .....	798, 799	AMILORIDE + HYDROCHLOROTHIAZIDE .....	122
<i>Alfaré(NT)</i> .....	802	AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE .....	810
ALFUZOSIN.....	1660	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE .....	810
<i>Algisite M 66000519(SN)</i> .....	1680	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID.....	810
<i>Algisite M 66000520(SN)</i> .....	1680	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID.....	810
<i>Algisite M 66000521(SN)</i> .....	1680	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE .....	810
<i>Algivon Plus CR4225(DJ)</i> .....	1680	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE.....	811
<i>Algivon Plus Ribbon &amp; Probe CR4231(DJ)</i> .....	1680	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID .....	811
<i>Alkeran(AS)</i> .....	283	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES ..	804, 805, 806, 807
<i>Allegron(RW)</i> .....	703	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN .....	811
<i>Allereze(AF)</i> .....	1672	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE .....	812
<i>Allevyn 66007637(SN)</i> .....	1682	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE.....	813
<i>Allevyn Adhesive 66000044(SN)</i> .....	1682	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE .....	813, 815
<i>Allevyn Ag Adhesive 66800073(SN)</i> .....	1685	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE .....	815, 816
<i>Allevyn Ag Adhesive 66800075(SN)</i> .....	1684		
<i>Allevyn Ag Adhesive 66800078(SN)</i> .....	1684		
<i>Allevyn Ag Gentle Border 66800460(SN)</i> .....	1685		
<i>Allevyn Ag Gentle Border 66800461(SN)</i> .....	1684		
<i>Allevyn Ag Gentle Border 66800462(SN)</i> .....	1684		
<i>Allevyn Ag Non-Adhesive 66800086(SN)</i> .....	1684		
<i>Allevyn Gentle 66800248(SN)</i> .....	1683		
<i>Allevyn Gentle Border 66800269(SN)</i> .....	1683		
<i>Allevyn Gentle Border 66800270(SN)</i> .....	1683		
<i>Allevyn Life 66801067(SN)</i> .....	1682		
<i>Allevyn Life 66801068(SN)</i> .....	1682		
<i>Allevyn Life 66801069(SN)</i> .....	1682		
<i>Allevyn Life 66801070(SN)</i> .....	1682		
<i>Allevyn Thin 66047576(SN)</i> .....	1687		
<i>Allevyn Thin 66047578(SN)</i> .....	1687		
<i>Allmercap(LM)</i> .....	287		
ALLOPURINOL.....	619, 620		
<i>Allopurinol APOTEX(GX)</i> .....	619, 620		
<i>Allopurinol Sandoz (SZ)</i> .....	619, 620		
<i>Allosig(RF)</i> .....	619, 620		
<i>Alodorm(AF)</i> .Palliative Care.....	841		
<i>Alodorm(AF)</i> .NERVOUS SYSTEM.....	658, 699, 700		
ALOGLIPTIN.....	80		
ALOGLIPTIN + METFORMIN.....	67		
<i>Aloxi(MF)</i> .....	47		
<i>Alpha Keri Bath Oil(MT)</i> .....	1653		
<i>Alpha Keri Lotion(MT)</i> .....	1653		
<i>AlphaClav Duo Forte(AF)</i> .....	243, 244		

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE .....	816, 817	<i>Amoxycilav AN 875/125 (EA)</i> .....	243, 244
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID .....	817	<i>AmoxyClav generichealth 875/125(HQ)</i> .....	243, 244
AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID .....	817	<i>AmoxyClav GH 875/125 (GQ)</i> .....	243, 244
AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE .....	818	AMPHOTERICIN B .....	33
AMINO ACID FORMULA WITHOUT PHENYLALANINE	818	AMPICILLIN .....	238
AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE .....	818	<i>Ampicyn(AF)</i> .....	238, 239
AMINO ACID SYNTHETIC FORMULA .....	789, 790, 791	<i>Anafranil 25(SZ)</i> .....	702
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS .....	792, 793	ANAKINRA .....	1010, 1248
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES .....	794, 795, 796, 797, 798	<i>Anamorph(RW)</i> .....	635, 638
AMIODARONE .....	114	<i>Anandron(SW)</i> .....	351
<i>Amiodarone Sandoz(SZ)</i> .....	114	<i>Anaprox 550(IX)</i> .....	616, 833
<i>Amipride 400(RW)</i> .....	688	<i>Anastrol(QA)</i> .....	351
<i>Amira 150(AF)</i> .....	708	ANASTROZOLE .....	351
<i>Amira 300(AF)</i> .....	708	<i>Anastrozole AN (EA)</i> .....	351
AMISULPRIDE .....	688	<i>Anastrozole FBM(FO)</i> .....	351
<i>Amisulpride 100 Winthrop(WA)</i> .....	688	<i>Anastrozole GH (GQ)</i> .....	351
<i>Amisulpride 200 Winthrop(WA)</i> .....	688	<i>Anastrozole Sandoz(SZ)</i> .....	351
<i>Amisulpride 400 Winthrop (WA)</i> .....	688	<i>Andepa(EL)</i> .....	710
<i>Amisulpride AN (EA)</i> .....	688	<i>Andriol Testocaps(MK)</i> .....	214
<i>Amisulpride AN(EA)</i> .....	688	<i>Androcur(BN)</i> .....	
<i>Amisulpride Sandoz (SZ)</i> .....	688	.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	349
<i>Amisulpride Sandoz(SZ)</i> .....	688	.GENITO URINARY SYSTEM AND SEX HORMONES .....	220, 221
AMITRIPTYLINE .....	701	<i>Androcur-100(BN)</i> .....	
<i>Amitriptyline Alphapharm 10(AL)</i> .....	701	.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	349
<i>Amitriptyline Alphapharm 25(AL)</i> .....	701	.GENITO URINARY SYSTEM AND SEX HORMONES .....	220
<i>Amitriptyline Alphapharm 50(AL)</i> .....	701	<i>Androderm(GN)</i> .....	212
<i>Amlo 10(RW)</i> .....	128	<i>AndroForte 5(LX)</i> .....	212
<i>Amlo 5(RW)</i> .....	128	<i>Anginine Stabilised(RW)</i> .....	116
AMLODIPINE .....	128	<i>Angiomax(XM)</i> .....	102
AMLODIPINE + ATORVASTATIN .....	188	<i>Anoro Ellipta 62.5/25(GK)</i> .....	743
AMLODIPINE + VALSARTAN .....	150	<i>Anpec 40(AF)</i> .....	130
AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE .....	151	<i>Anpec 80(AF)</i> .....	131
<i>Amlodipine Amneal (EF)</i> .....	128	<i>Antenex 2(AF)</i> .....	697, 840
<i>Amlodipine AN(EA)</i> .....	128	<i>Antenex 5(AF)</i> .....	697, 840
<i>Amlodipine GH (GQ)</i> .....	128	ANTERONE 100(RW) .....	
<i>Amlodipine Sandoz(SZ)</i> .....	128	.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	349
AMMONIUM + SENEGA ROOT .....	1671	.GENITO URINARY SYSTEM AND SEX HORMONES .....	220
AMOROLFINE .....	1651	ANTERONE 50(RW) .....	
AMOXICLAV AMNEAL 500/125(ED) .....	244, 245	.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	349
AMOXICLAV AMNEAL 875/125(ED) .....	243, 244	.GENITO URINARY SYSTEM AND SEX HORMONES .....	220, 221
<i>Amoxil Forte(AS)</i> .....	238	<i>Anthel 125(AF)</i> .....	735
<i>Amoxil(AS)</i> .....	236, 237, 238	<i>Anthel 250(AF)</i> .....	735
AMOXYCILLIN .....	236, 238	<i>Antroquoril(FR)</i> .....	197
AMOXYCILLIN + CLAVULANIC ACID .....	243, 244	<i>Anusol(JT)</i> .....	1650
<i>Amoxycillin AN (EA)</i> .....	237	<i>Apidra SoloStar (SW)</i> .....	62
<i>Amoxycillin generichealth 500(GQ)</i> .....	237	<i>Apidra(AV)</i> .....	62
<i>Amoxycillin Ranbaxy (RA)</i> .....	237	<i>Apidra(SW)</i> .....	62
<i>Amoxycillin Ranbaxy(RA)</i> .....	237	APIXABAN .....	104, 105, 106
<i>Amoxycillin Sandoz (SZ)</i> .....	237, 238	<i>APO- Hydroxychloroquine(TX)</i> .....	618
<i>Amoxycillin Sandoz(BG)</i> .....	238	<i>APO- Paracetamol/Codeine 500/30(TX)</i> .....	645, 646
<i>Amoxycillin Sandoz(SZ)</i> .....	237	<i>APO-Adefovir(TX)</i> .....	1323
<i>Amoxyclav AN 500/125 (EA)</i> .....	244, 245	<i>APO-Alendronate Plus D3 70 mg/140 mcg (TX)</i> .....	1663
		<i>APO-Alendronate Plus D3 70 mg/140 mcg(TX)</i> .....	625
		<i>APO-Alendronate Plus D3 70 mg/70 mcg (TX)</i> .....	1664
		<i>APO-Alendronate Plus D3 70 mg/70 mcg(TX)</i> .....	626
		<i>APO-Alendronate Plus D3 and Calcium(TX)</i> .....	1664
		<i>APO-Alendronate(TX)</i> .....	621
		<i>APO-Allopurinol (TX)</i> .....	619, 620
		<i>APO-Amisulpride (TX)</i> .....	688
		<i>APO-Amisulpride(TX)</i> .....	688
		<i>APO-Amitriptyline 10 (TX)</i> .....	701
		<i>APO-Amitriptyline 25 (TX)</i> .....	701

APO-Amitriptyline 50 (TX).....	701	APO-Fluoxetine(TX).....	706
APO-Amlodipine (TX).....	128	APO-Fluvoxamine(TX).....	706
APO-Amlodipine/Atorvastatin 10/10(TX).....	189	APO-Fosinopril HCTZ 20/12.5(TX).....	138
APO-Amlodipine/Atorvastatin 10/20(TX).....	188	APO-Fosinopril(TX).....	132
APO-Amlodipine/Atorvastatin 10/40(TX).....	189	APO-Frusemide(TX).....	121
APO-Amlodipine/Atorvastatin 10/80(TX).....	189	APO-Gabapentin(TX)	
APO-Amlodipine/Atorvastatin 5/10(TX).....	189	Repatriation Pharmaceutical Benefits Scheme.....	1666
APO-Amlodipine/Atorvastatin 5/20(TX).....	189	APO-Gabapentin(TX)	
APO-Amlodipine/Atorvastatin 5/40(TX).....	189	NERVOUS SYSTEM.....	662, 663
APO-Amlodipine/Atorvastatin 5/80(TX).....	190	APO-Galantamine MR(TX).....	721, 722, 723
APO-Amoxicillin (TX).....	237	APO-Gliclazide MR(TX).....	66
APO-Amoxicillin and Clavulanic Acid 125/31.25(TX) ...	244, 245	APO-Glimepiride(TX).....	66, 67
APO-Amoxicillin and Clavulanic Acid 400/57(TX) .	243, 244	APOHEALTH Osteo Relief Paracetamol 665 mg(TX) ...	651, 839
APO-Amoxicillin and Clavulanic Acid(TX).....	243, 244	APO-Ibuprofen 400(TX).....	614, 832
APO-Amoxicillin(TX).....	237, 238	APO-Imiquimod (TX).....	207, 1656, 1657
APO-Amoxicillin/ Clavulanic Acid 500/125(TX).....	244, 245	APO-Indapamide SR(TX).....	120
APO-Anastrozole (TX).....	351	APO-Ipratropium (TX).....	745
APO-Aripiprazole(TX).....	689	APO-Irbesartan (TX).....	142, 143
APO-Atenolol(TX).....	124	APO-Irbesartan HCTZ (TX).....	146, 147
APO-Atomoxetine(TX).....	714, 715	APO-Isotretinoin(TX).....	205, 206
APO-Atorvastatin(TX).....	153, 154, 155	APO-Itraconazole(TX).....	268
APO-Azathioprine(TX).....	608	APO-Lamotrigine(TX).....	665, 666
APO-Azithromycin(TX)		APO-Lansoprazole ODT(TX).....	37
Repatriation Pharmaceutical Benefits Scheme.....	1661	APO-Lansoprazole(TX).....	37, 38
APO-Azithromycin(TX)		APO-Latanoprost(TX).....	761
ANTIINFECTIVES FOR SYSTEMIC USE.....	254	APO-Latanoprost/Timolol 0.05/5(TX).....	761, 762
SENSORY ORGANS.....	750	APO-Lercanidipine(TX).....	129
APO-Baclofen(TX).....	619	APO-Letrozole(TX).....	352
APO-Bicalutamide(TX).....	348	APO-Levetiracetam(TX).....	666, 667
APO-Bisoprolol(TX).....	124, 125	APO-Lisinopril(TX).....	133
APOC-5FU(TX).....	1662	APO-MACROGOL plus ELECTROLYTES(TX).....	53, 830
APO-Cabergoline(TX).....	208, 209	APO-Meloxicam(TX).....	612, 613
APO-Calcitriol(TX)		APO-Memantine(TX).....	725, 726
ALIMENTARY TRACT AND METABOLISM.....	90	APO-Metformin 1000(TX).....	64
MUSCULO-SKELETAL SYSTEM.....	628	APO-Metformin 500(TX).....	65
APO-Candesartan (TX).....	141, 142	APO-Metformin 850(TX).....	65
APO-Candesartan HCTZ 16/12.5 (TX).....	145	APO-Metformin XR 1000(TX).....	65
APO-Candesartan HCTZ 32/12.5 (TX).....	145	APO-Metformin XR 500(TX).....	64
APO-Candesartan HCTZ 32/25 (TX).....	146	APO-Metoclopramide(TX).....	42
APO-Carvedilol(TX).....	127	APO-Metoprolol(TX).....	126
APO-Cefaclor (TX).....	249	Apomine Solution for Infusion(PF).....	1053, 1291
APO-Cefaclor CD(TX).....	249	APO-Mirtazapine(TX).....	711
APO-Celecoxib(TX).....	617	APO-Modafinil(TX).....	718
APO-Cephalexin(TX).....	245, 246, 247	APO-Montelukast(TX).....	748, 749
APO-Ciprofloxacin(TX).....	260, 261	APOMORPHINE.....	1052, 1291
APO-Citalopram(TX).....	703	APO-Mycophenolate(TX).....	366, 367, 946, 1184, 1185
APO-Clarithromycin(TX).....	254, 912, 1149	APO-Naltrexone(TX).....	730
APO-Clindamycin(TX).....	257, 258	APO-Nifedipine XR(TX).....	130
APO-Clonidine(TX).....	119	APO-Olanzapine ODT(TX).....	683, 684, 685
APO-Clopidogrel(TX).....	98, 99, 1649	APO-Olanzapine(TX).....	681, 682, 683
APO-Clopidogrel/Aspirin 75/100(TX).....	100	APO-Olmesartan(TX).....	143, 144
APO-Clotrimazole 3 Day Cream(TX).....	1657	APO-Olmesartan/HCTZ 20/12.5(TX).....	148
APO-Clotrimazole 6 Day Cream(TX).....	1658	APO-Olmesartan/HCTZ 40/12.5(TX).....	148
APO-Desvenlafaxine MR(TX).....	709	APO-Olmesartan/HCTZ 40/25(TX).....	148
APO-Diazepam (TX).....	697, 840	APO-Omeprazole(TX).....	38, 39
APO-Diazepam(TX).....	697, 840	APO-Ondansetron(TX).....	44, 45
APO-Diclofenac(TX).....	610, 611, 832	APO-Oxazepam (TX).....	698, 699, 840
APO-Donepezil(TX).....	719, 720	APO-Pantoprazole(TX).....	39, 40
APO-Doxycycline(TX).....	233, 234, 235, 236	APO-Paracetamol(TX).....	650, 651, 1666
APO-Duloxetine (TX).....	710	APO-Paroxetine(TX).....	707
APO-Dutasteride(TX).....	223	APO-Perindopril Arginine(TX).....	133, 134
APO-Enalapril (TX).....	132	APO-Perindopril Arginine/Amlodipine 10/10(TX).....	139
APO-Escitalopram(TX).....	704	APO-Perindopril Arginine/Amlodipine 10/5(TX).....	140
APO-Exemestane(TX).....	352	APO-Perindopril Arginine/Amlodipine 5/10(TX).....	140
APO-Famciclovir(TX).....	274, 275, 276	APO-Perindopril Arginine/Amlodipine 5/5(TX).....	140
APO-Fentanyl(TX).....	642, 643, 644	APO-Perindopril(TX).....	134
APO-Finasteride(TX).....	1661	APO-Pramipexole ER(TX).....	675
APO-Flucloxacillin(TX).....	242, 243	APO-Pramipexole(TX).....	674
APO-Fluconazole(TX).....	265	APO-Pravastatin(TX).....	156, 157, 158

APO-Prazosin(TX)	119	ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID	
APO-Pregabalin(TX)	652	WITH CARBOHYDRATE	818
APO-Prochlorperazine(TX)	49, 50	Aranesp SureClick(AN)	850, 851, 1087, 1088
APO-Propranolol(TX)	123, 124	Aranesp(AN)	850, 851, 1087, 1088
APO-Quetiapine XR(TX)	686, 687	Aratac 100(AF)	114
APO-Quetiapine(TX)	686, 687, 688	Aratac 200 (AF)	114
APO-Quinapril (TX)	135	Arava (SW)	366
APO-Quinapril(TX)	135	Arazil (AF)	719, 720
APO-Rabeprazole(TX)	40, 41	ARDIX GLICLAZIDE 60mg MR(RX)	66
APO-Raloxifene(TX)	630	Arginaid Extra(NT)	1673
APO-Ramipril(TX)	135, 136, 137	Arginaid(NT)	1673
APO-Ranitidine(TX)	34	Arginine 2000(VF)	819
APO-Riluzole(TX)	732	Arginine 500(VF)	819
APO-Risedronate (TX)	623, 1663	Arginine 5000(VF)	819
APO-Risedronate(TX)	623	ARGININE WITH CARBOHYDRATE	818
APO-Risperidone(TX)	692, 693, 694, 695, 696	Arianna 1(AF)	351
APO-Rizatriptan(TX)	654	Aricept(PF)	719, 720, 721
APO-Rosuvastatin(TX)	158, 159, 160, 161, 162, 163	Aridon 10(RW)	719, 720
APO-Roxithromycin(TX)	256, 257	Aridon 5(RW)	719, 720
Aporyl(TX)	1651	Aridon APN 10 (RF)	719, 720
APO-Salbutamol(TX)	26, 737	Aridon APN 5 (RF)	719, 720
APO-Sertraline(TX)	707	Arimidex (AP)	351
APO-Sildenafil PHT(TX)	899, 1136	ARIPIPRAZOLE	689
APO-Sildenafil(TX)	1658, 1659	Aripiprazole AN (EA)	689
APO-Simvastatin(TX)	163, 164, 165, 166	Aripiprazole GH(GQ)	689
APO-Sotalol(TX)	114, 115	Aripiprazole Sandoz (SZ)	689
APO-Sumatriptan(TX)	655	Aristocort 0.02%(QA)	194, 195
APO-Telmisartan HCTZ 40/12.5(TX)	148	Arixtra(AS)	110
APO-Telmisartan HCTZ 80/12.5(TX)	148	ARMODAFINIL	713
APO-Telmisartan HCTZ 80/25(TX)	149	Aromasin(PF)	352
APO-Telmisartan(TX)	144	Aropax(AS)	707
APO-Temazepam(TX)	700, 701, 841	Arrow Pharma Pty Ltd(RW)	271
APO-Temozolomide(TX)	284, 285, 286	Artane(RW)	670
APO-Terbinafine(TX)	192	ARTEMETHER + LUMEFANTRINE	733
APOTEX-Pantoprazole (GX)	39, 40	Arthrexin(AF)	611, 612, 832
APOTEX-Pioglitazone (TX)	79	Artige(NM)	717
APO-Topiramate(TX)	668, 669	Asacol(EU)	58
APO-Tramadol SR(TX)	647, 648	Asartan HCT 16/12.5(DO)	145
APO-Tramadol(TX)	648, 649	Asartan HCT 32/12.5(DO)	145
APO-Tranexamic Acid(TX)	110	Asartan HCT 32/25(DO)	146
APO-Ursodeoxycholic acid(TX)	50	Asasantin SR(BY)	101
APO-Valaciclovir(TX)	277, 278, 913, 1151	ASENAPINE	680
APO-Valsartan HCTZ 160/12.5(TX)	149	Asmol 2.5 uni-dose(AF)	26, 737
APO-Valsartan HCTZ 160/25(TX)	149	Asmol 5 uni-dose(AF)	26, 737
APO-Valsartan HCTZ 320/12.5(TX)	150	Asmol CFC-free(AL)	26, 737
APO-Valsartan HCTZ 320/25(TX)	150	Aspalgin 40(QA)	1665
APO-Valsartan HCTZ 80/12.5(TX)	149	Aspicillin VK(QA)	239, 240
APO-Valsartan(TX)	144	Aspen Methadone Syrup(QA)	
APO-Venlafaxine XR(TX)	712	Opiate Dependence Treatment Program	1633
APO-Ziprasidone(TX)	679, 680	Palliative Care	838
APO-Zoledronic Acid(TX)	1052, 1291	Aspen Pharma Pty Ltd(QA)	716
APO-Zolmitriptan(TX)	656	ASPIRIN	
APO-Zonisamide(TX)	670	BLOOD AND BLOOD FORMING ORGANS	97, 98
APO-Zopiclone(TX)	1669	NERVOUS SYSTEM	650
APRACLONIDINE	755	Repatriation Pharmaceutical Benefits Scheme	1648
APREPITANT	48	ASPIRIN + CODEINE	1665
Aptamil Gold+ De-Lact(NU)	809	Astrix(YN)	1648
Aptamil Gold+ Pepti-Junior(NU)	801	Astzul(JU)	351
Aptivus(BY)	1322	Atacand Plus 16/12.5(AP)	146
Aquacare H.P. (AG)	1652	Atacand Plus 32/12.5(AP)	145
Aquacel 403770(CC)	1689	Atacand Plus 32/25(AP)	146
Aquacel Ag 403708(CC)	1690	Atacand(AP)	141, 142
Aquacel Ag 403710(CC)	1690	Ataris 10(AF)	366
Aquacel Ag 403771(CC)	1690	Ataris 20(AF)	366
Aquacel Extra 420672(CC)	1689	ATAZANAVIR	1319
Aquacel Extra 420673(CC)	1690	ATAZANAVIR + COBICISTAT	1320
Aquacel Foam Adhesive(CC)	1689	ATELVIA ONCE-A-MONTH (GN)	623
Aquacel Foam Non-Adhesive(CC)	1689	ATENOLOL	124
Aquasun Lotion SPF 18(PF)	1653	Atenolol Amneal (EF)	124
Arabloc(AV)	366	Atenolol GH (GQ)	124

<i>Atenolol RBX(RA)</i> .....	124	<i>Aurozapine 45 (DO)</i> .....	711
<i>Atenolol Sandoz (SZ)</i> .....	124	<i>Auscap Aspen (RW)</i> .....	706
<i>Atenolol-AFT(AE)</i> .....	124	<i>Ausfam 20(RW)</i> .....	34
<i>Atenolol-GA(ED)</i> .....	124	<i>Ausfam 40(RW)</i> .....	33
<i>ATOMERRA (RW)</i> .....	714, 715	<i>Ausgem(RW)</i> .....	167
<i>ATOMOXETINE</i> .....	714	<i>Ausran (RW)</i> .....	34
<i>Atomoxetine Amneal(EA)</i> .....	714, 715	<i>Austrapen (AL)</i> .....	238, 239
<i>Atomoxetine Sandoz (SZ)</i> .....	714, 715	<i>Austrapen(AL)</i> .....	238
<i>ATORVASTATIN</i> .....	153, 154	<i>Avandamet(GK)</i> .....	73, 74
<i>Atorvastatin Amneal (EF)</i> .....	153, 154, 155	<i>Avanza SolTab(MK)</i> .....	711, 712
<i>Atorvastatin GH(GQ)</i> .....	153, 154, 155	<i>Avanza(MK)</i> .....	711
<i>Atorvastatin Sandoz (SZ)</i> .....	153, 154, 155	<i>Avapro HCT 150/12.5(AV)</i> .....	147
<i>Atorvastatin SCP 10(RZ)</i> .....	153, 155	<i>Avapro HCT 300/12.5(AV)</i> .....	147
<i>Atorvastatin SCP 20(RZ)</i> .....	154, 155	<i>Avapro HCT 300/25(AV)</i> .....	147
<i>Atorvastatin SCP 40(RZ)</i> .....	153, 154	<i>Avapro(AV)</i> .....	143
<i>Atorvastatin SCP 80(RZ)</i> .....	154, 155	<i>Avodart (GK)</i> .....	223
<i>Atorvastatin SZ (HX)</i> .....	153, 154, 155	<i>Avodart(GK)</i> .....	1660
<i>ATOVAQUONE</i> .....	732	<i>Avonex(BD)</i> .....	355
<i>ATOVAQUONE + PROGUANIL</i> .....	733	<i>Axiron(LY)</i> .....	212
<i>Atozet(MK)</i> .....	175, 178	<i>Axit 15 (AF)</i> .....	711
<i>Atrauman 499513(HR)</i> .....	1692	<i>Axit 30(AF)</i> .....	711
<i>Atrauman Ag 499572(HR)</i> .....	1693	<i>Axit 45(AF)</i> .....	711
<i>Atripia(GI)</i> .....	1334	<i>AXITINIB</i> .....	292, 293
<b>ATROPINE SULFATE</b>		<i>Aylide 1 (AF)</i> .....	67
<b>.ALIMENTARY TRACT AND METABOLISM</b> .....	42	<i>Aylide 2 (AF)</i> .....	66
.Prescriber Bag.....	23	<i>Aylide 3 (AF)</i> .....	66
<b>.SENSORY ORGANS</b> .....	763	<i>Aylide 4 (AF)</i> .....	66
<i>Atropt(QA)</i> .....	763	<b>AZACITIDINE</b> .....	918, 919, 1155, 1156
<i>Atrovent Adult(BY)</i> .....	745	<i>Azacitidine Accord(OC)</i> .....	919, 1156, 1157
<i>Atrovent Nasal Aqueous(VZ)</i> .....	1671	<b>AZACITIDINE DR.REDDY'S (RI)</b> .....	919, 1156, 1157
<i>Atrovent Nasal Forte(VZ)</i> .....	1671	<i>Azadine(RZ)</i> .....	919, 1156, 1157
<i>Atrovent(BY)</i> .....	745	<i>Azapin (RW)</i> .....	608
<i>Aubagio(GZ)</i> .....	368	<i>Azarga(NV)</i> .....	757, 758
<i>Augmentin Duo 400(AS)</i> .....	243, 244	<i>Azastrole (ER)</i> .....	351
<i>Augmentin Duo forte(AS)</i> .....	243, 245	<b>AZATHIOPRINE</b> .....	608
<i>Augmentin Duo(AS)</i> .....	244, 245	<i>Azathioprine AN(EA)</i> .....	608
<i>Augmentin(AS)</i> .....	244, 245	<i>Azathioprine GH (GQ)</i> .....	608
<b>AURANOFIN</b> .....	618	<i>Azathioprine Sandoz(SZ)</i> .....	608
<i>Auro-Amlodipine 10(DO)</i> .....	128	<i>Azilect(TB)</i> .....	676
<i>Auro-Amlodipine 5(DO)</i> .....	128	<b>AZITHROMYCIN</b>	
<i>Auro-Candesartan 16(DO)</i> .....	141	<b>.ANTIINFECTIVES FOR SYSTEMIC USE</b> .....	253, 254
<i>Auro-Candesartan 32(DO)</i> .....	141	.Highly Specialised Drugs Program (Private Hospital).....	911
<i>Auro-Candesartan 4(DO)</i> .....	141	.Highly Specialised Drugs Program (Public Hospital).....	1149
<i>Auro-Candesartan 8(DO)</i> .....	142	.Repatriation Pharmaceutical Benefits Scheme.....	1661
<i>Auro-Citalopram 20 (DO)</i> .....	703	<b>.SENSORY ORGANS</b> .....	750
<i>Auro-Citalopram 40 (DO)</i> .....	703	<i>Azithromycin Mylan (AF)</i> .....	254, 750
<i>Auro-Famciclovir 125 (DO)</i> .....	274	<i>Azithromycin Sandoz(SZ)</i>	
<i>Auro-Famciclovir 250 (DO)</i> .....	274, 275	.Repatriation Pharmaceutical Benefits Scheme.....	1661
<i>Auro-Famciclovir 500 (DO)</i> .....	275, 276	<i>Azithromycin Sandoz(SZ)</i>	
<i>Auro-Finasteride(DO)</i> .....	1661	<b>.ANTIINFECTIVES FOR SYSTEMIC USE</b> .....	254
<i>Auro-Lisinopril 10 (DO)</i> .....	133	<b>.SENSORY ORGANS</b> .....	750
<i>Auro-Lisinopril 20 (DO)</i> .....	133	<i>Azithromycin-GA (EA)</i> .....	1661
<i>Auro-Lisinopril 5 (DO)</i> .....	133	<i>Azol 100(AF)</i> .....	221
<i>Auro-Montelukast Tabs 4 (DO)</i> .....	748	<i>Azol 200(AF)</i> .....	221
<i>Auro-Montelukast Tabs 5 (DO)</i> .....	749	<i>Azopt(NV)</i> .....	757
<i>Auro-Pravastatin 10 (DO)</i> .....	156, 157	<b>BACILLUS CALMETTE AND GUERIN-TICE STRAIN</b> .....	357
<i>Auro-Pravastatin 20 (DO)</i> .....	156, 157	<b>BACLOFEN</b> .....	619, 1050, 1288, 1289
<i>Auro-Pravastatin 40 (DO)</i> .....	156, 158	<i>Bactecal(DZ)</i> .....	1051, 1289
<i>Auro-Pravastatin 80 (DO)</i> .....	157, 158	<i>Bactigras 7457(SN)</i> .....	1685
<i>Aurorix 300 mg(HM)</i> .....	708	<i>Bactrim DS(RO)</i> .....	253
<i>Aurorix(HM)</i> .....	709	<i>Bactrim(RO)</i> .....	253
<i>Auro-Sertraline 100 (DO)</i> .....	707	<i>Bactroban(GK)</i>	
<i>Auro-Sertraline 100(DO)</i> .....	708	.Repatriation Pharmaceutical Benefits Scheme.....	1654
<i>Auro-Sertraline 50 (DO)</i> .....	707	<i>Bactroban(GK)</i>	
<i>Auro-Sertraline 50(DO)</i> .....	708	<b>.RESPIRATORY SYSTEM</b> .....	736
<i>Auro-Simvastatin 10 (DO)</i> .....	163, 165	<b>BALSALAZIDE</b> .....	57
<i>Auro-Simvastatin 20 (DO)</i> .....	164, 166	<b>BANDAGE ABSORBENT WOOL</b> .....	1674
<i>Auro-Simvastatin 40 (DO)</i> .....	164, 166	<b>BANDAGE CALICO</b> .....	1674
<i>Auro-Simvastatin 80 (DO)</i> .....	164, 165	<b>BANDAGE COMPRESSION</b> .....	1674, 1675
<i>Aurozapine 30 (DO)</i> .....	711	<b>BANDAGE RETENTION COHESIVE HEAVY</b> .....	1675

BANDAGE RETENTION COHESIVE LIGHT.....	1675	<i>Bimtop (QA)</i> .....	760
BANDAGE RETENTION COTTON CREPE .....	1675	<i>Biodone Forte (MW)</i> .....	1633
BANDAGE TUBULAR .....	1676	<i>Bion Tears(NV)</i> .....	776
BANDAGE TUBULAR FINGER.....	1676	BIPERIDEN .....	670
BANDAGE TUBULAR LIGHT WEIGHT.....	1677	BISACODYL	
BANDAGE TUBULAR LONG STOCKING.....	1677	.ALIMENTARY TRACT AND METABOLISM .....	50, 51, 53
BANDAGE TUBULAR SHORT STOCKING .....	1677	.Palliative Care.....	829, 831
BANDAGE ZINC PASTE .....	1677, 1678	.Repatriation Pharmaceutical Benefits Scheme .....	1644
<i>Baraclude(BQ)</i> .....	1324, 1325	<i>Bisalax(AS)</i> .....	54, 831
<i>Barbloc 5(AF)</i> .....	123	BISOPROLOL .....	124
<i>basecal 100(VF)</i> .....	819	<i>Bisoprolol AN (EA)</i> .....	124, 125
<i>basecal 200(VF)</i> .....	819	<i>Bisoprolol generichealth(GQ)</i> .....	124, 125
<i>Baxter Healthcare Pty Ltd(BX)</i> .....	1650	<i>Bisoprolol Sandoz (SZ)</i> .....	124, 125
BECLOMETASONE .....	743	<i>Bispro 10(AF)</i> .....	125
<i>Bemfola(FX)</i> .....	218, 1627, 1628	<i>Bispro 2.5(AF)</i> .....	124
<i>BenPen(CS)</i> .....	23, 239	<i>Bispro 5(AF)</i> .....	125
BENZATHINE BENZYL PENICILLIN.....	239	BIVALIRUDIN .....	102
BENZATROPINE .....	23, 670	<i>Bivalirudin APOTEX (TX)</i> .....	102
BENZHEXOL .....	670	<i>Blooms the Chemist Amlodipine (IB)</i> .....	128
<i>Benztrop(PL)</i> .....	671	<i>Blooms the Chemist Amlodipine/Atorvastatin 10/10 (IB)</i> .....	189
<i>Benztropine Omega(FK)</i> .....	23, 670	<i>Blooms the Chemist Amlodipine/Atorvastatin 10/20 (IB)</i> .....	188
BENZYDAMINE .....	33, 829	<i>Blooms the Chemist Amlodipine/Atorvastatin 10/40 (IB)</i> .....	189
BENZYL PENICILLIN .....	23, 239	<i>Blooms the Chemist Amlodipine/Atorvastatin 10/80 (IB)</i> .....	189
<i>Beprol 10 (DO)</i> .....	125	<i>Blooms the Chemist Amlodipine/Atorvastatin 5/10 (IB)</i> .....	189
<i>Beprol 2.5 (DO)</i> .....	124	<i>Blooms the Chemist Amlodipine/Atorvastatin 5/20 (IB)</i> .....	189
<i>Beprol 5 (DO)</i> .....	125	<i>Blooms the Chemist Amlodipine/Atorvastatin 5/40 (IB)</i> .....	189
<i>Betadine Antiseptic Liquid(SW)</i> .....	1655	<i>Blooms the Chemist Amlodipine/Atorvastatin 5/80 (IB)</i> .....	190
<i>Betaferon(BN)</i> .....	356	<i>Blooms the Chemist Atorvastatin(IB)</i> .....	153, 154, 155
BETAINE .....	92	<i>Blooms the Chemist Candesartan (IB)</i> .....	141, 142
BETAINE + POLYAMINOPROPYL BIGUANIDE .....	1678	<i>Blooms the Chemist Candesartan HCTZ 16/12.5 (IB)</i> .....	145
<i>Betaloc(AP)</i> .....	126	<i>Blooms the Chemist Candesartan HCTZ 32/12.5 (IB)</i> .....	145
BETAMETHASONE ACETATE + BETAMETHASONE		<i>Blooms the Chemist Candesartan HCTZ 32/25 (IB)</i> .....	146
SODIUM PHOSPHATE.....	226	<i>Blooms the Chemist Celecoxib (IB)</i> .....	617
BETAMETHASONE DIPROPIONATE.....	195, 196	<i>Blooms the Chemist Clopidogrel (IB)</i> .....	98, 99, 1649
BETAMETHASONE VALERATE .....	197, 198, 1655	<i>Blooms the Chemist Escitalopram (IB)</i> .....	704
<i>betaquik(VF)</i> .....	788	<i>Blooms the Chemist Fluoxetine(IB)</i> .....	706
<i>Betavit(PP)</i> .....	90, 1647	<i>Blooms the Chemist Irbesartan HCTZ 150/12.5(IB)</i> .....	147
BETAXOLOL .....	758, 759	<i>Blooms the Chemist Irbesartan HCTZ 300/12.5(IB)</i> .....	146
BETHANECHOL .....	727	<i>Blooms the Chemist Irbesartan HCTZ 300/25(IB)</i> .....	147
<i>Betnovate 1/2(QA)</i> .....	197, 198	<i>Blooms the Chemist Irbesartan(IB)</i> .....	142, 143
<i>Betnovate 1/5(QA)</i> .....	197	<i>Blooms the Chemist Lercanidipine (IB)</i> .....	129
<i>Betnovate(QA)</i> .....	1655	<i>Blooms the Chemist Metformin XR 1000 (IB)</i> .....	65
<i>Betoptic S(NV)</i> .....	759	<i>Blooms the Chemist Metformin XR 500 (IB)</i> .....	64
<i>Betoptic(NV)</i> .....	759	<i>Blooms the Chemist Perindopril (IB)</i> .....	134
<i>BetoQuin(NM)</i> .....	758, 759	<i>Blooms The Chemist Pregabalin (IB)</i> .....	652
<i>Bi ELIGARD CP(TL)</i>		<i>Blooms the Chemist Rosuvastatin (IB)</i> .....	158, 159, 160, 161, 162, 163
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Blooms the Chemist Venlafaxine XR (IB)</i> .....	712
AGENTS.....	346, 347, 350, 351	<i>Bondronat(RO)</i> .....	622, 1051, 1290
<i>Biatain Adhesive 3420(CT)</i> .....	1686	<i>Bonefos 800 mg(BN)</i> .....	622
<i>Biatain Adhesive 3423(CT)</i> .....	1687	<i>Bonefos(BN)</i> .....	622
<i>Biatain Ag 9622(CT)</i> .....	1693	BOSENTAN.....	858, 864, 1096, 1101
<i>Biatain Ag 9632(CT)</i> .....	1693	<i>Bosentan APOTEX(TX)</i> .....	864, 869, 1101, 1107
<i>Biatain Non-adhesive 3410(CT)</i> .....	1686	<i>Bosentan GH(GQ)</i> .....	864, 1101
<i>Biatain Non-adhesive 3413(CT)</i> .....	1686	<i>Bosentan Mylan (AF)</i> .....	864, 1101
<i>Biaxsig (AV)</i> .....	256, 257	<i>Bosentan Mylan(AF)</i> .....	869, 1107
<i>Bicalide (JU)</i> .....	348	<i>Bosentan RBX (RA)</i> .....	869, 1107
<i>Bicalox(ER)</i> .....	348	<i>Bosentan RBX(RA)</i> .....	864, 1101
BICALUTAMIDE .....	348	<i>Bosentan Sandoz (SZ)</i> .....	864, 1101
<i>Bicalutamide AN (EA)</i> .....	348	<i>Bosentan Sandoz(SZ)</i> .....	869, 1107
BICARBONATE .....	222	BOSENTAN-DRLA (RZ).....	864, 869, 1101, 1107
BICARBONATE + CITRIC ACID + TARTARIC ACID ..	1660	BOSLEER (RW) .....	869, 1107
<i>Bicard 10(RW)</i> .....	125	BOSLEER(RW) .....	864, 1101
<i>Bicard 2.5(RW)</i> .....	124	<i>Botox(AG)</i> .....	1341, 1342, 1343, 1344
<i>Bicard 5(RW)</i> .....	125	BOTULINUM TOXIN TYPE A .....	1341, 1342, 1343
<i>Bicillin L-A(PF)</i> .....	239	<i>Brenzys(MK)</i> .....	463, 465, 466, 469, 486, 488, 490, 498, 501, 505, 508, 525
<i>Bicor(AL)</i> .....	124, 125	<i>Breo Ellipta 100/25(GK)</i> .....	742
<i>Biltricide(BN)</i> .....	734	<i>Breo Ellipta 200/25(GK)</i> .....	741
BIMATOPROST.....	760	<i>Bretaris Genuair(FK)</i> .....	744
BIMATOPROST + TIMOLOL .....	760		
<i>Bimatoprost Sandoz(SZ)</i> .....	760		

<i>Brevinor</i> (PF) .....	210	<i>Calcipotriol/Betamethasone Sandoz 50/500</i> (SZ) .....	193
<i>Brevinor-1</i> (PF) .....	210	<i>Calciprox</i> (ER) .....	90, 628
BREXPIRAZOLE .....	690	<i>Calci-Tab 600</i> (AE) .....	91
<i>Bricanyl Turbuhaler</i> (AP) .....	738	CALCITRIOL	
<i>Bricanyl</i> (AP) .....	747	ALIMENTARY TRACT AND METABOLISM .....	89
<i>Brilinta</i> (AP) .....	101	MUSCULO-SKELETAL SYSTEM .....	628
<i>Brimica Genuair</i> (FK) .....	742	<i>Calcitriol AN</i> (EA)	
BRIMONIDINE .....	755	ALIMENTARY TRACT AND METABOLISM .....	90
BRIMONIDINE + TIMOLOL .....	755, 756	MUSCULO-SKELETAL SYSTEM .....	628
BRINZOLAMIDE .....	757	CALCIUM .....	90, 1647
BRINZOLAMIDE + BRIMONIDINE .....	757	CALCIUM CARBONATE + GLYCINE .....	1643
BRINZOLAMIDE + TIMOLOL .....	757	<i>Calcium Folinat Ebewe</i> (SZ) .....	785, 786
<i>BrinzoQuin</i> (NM) .....	757	<i>Calindamin</i> (RW) .....	257, 258
BROMAZEPAM .....	1668	<i>Calmurid</i> (OL) .....	1652
BROMOCRIPTINE		<i>Calutex</i> (QA) .....	348
GENITO URINARY SYSTEM AND SEX HORMONES		<i>Camino Pro Bettermilk</i> (QH) .....	821
.....	208	<i>Camino Pro Complete</i> (QH) .....	821
NERVOUS SYSTEM .....	673	<i>Campral</i> (AF) .....	730
<i>bronchitol</i> (XA) .....	1071, 1310	CANDESAN COMBI 16/12.5(RF) .....	145
<i>Brufen</i> (GO) .....	614, 832	CANDESAN COMBI 32/12.5(RF) .....	145
<i>BSN 2902165</i> (BV) .....	1693	CANDESAN COMBI 32/25(RF) .....	146
<i>Budamax Aqueous</i> (PM) .....	1670	CANDESAN(RF) .....	141, 142
<i>Budonofalk</i> (OA) .....	57	CANDESARTAN .....	141
BUDESONIDE		CANDESARTAN + HYDROCHLOROTHIAZIDE .....	145
ALIMENTARY TRACT AND METABOLISM .....	56	<i>Candesartan AN</i> (EA) .....	141, 142
Repatriation Pharmaceutical Benefits Scheme .....	1670	<i>Candesartan Aspen 16</i> (RW) .....	141
RESPIRATORY SYSTEM .....	743	<i>Candesartan Aspen 32</i> (RW) .....	141
BUDESONIDE + EFORMOTEROL .....	738, 739	<i>Candesartan Aspen 4</i> (RW) .....	141
BUPRENORPHINE		<i>Candesartan Aspen 8</i> (RW) .....	142
NERVOUS SYSTEM .....	644	<i>Candesartan Combi Aspen 16/12.5</i> (RW) .....	145
Opiate Dependence Treatment Program .....	1632	<i>Candesartan Combi Aspen 32/12.5</i> (RW) .....	145
Palliative Care .....	838	<i>Candesartan Combi Aspen 32/25</i> (RW) .....	146
BUPRENORPHINE + NALOXONE .....	1632	<i>Candesartan GH</i> (GQ) .....	141
BUPROPION .....	727	<i>Candesartan HCT GH 16/12.5</i> (GQ) .....	145
<i>Buscopan</i> (VZ) .....	24, 829, 1644	<i>Candesartan HCT GH 32/12.5</i> (GQ) .....	145
<i>Buspar</i> (QA) .....	1668	<i>Candesartan HCT GH 32/25</i> (GQ) .....	146
BUSPIRONE .....	1668	<i>Candesartan HCTZ AN 16/12.5</i> (EA) .....	145
BUSULFAN .....	283	<i>Candesartan HCTZ AN 32/12.5</i> (EA) .....	145
<i>Butamol 2.5</i> (QA) .....	26, 737	<i>Candesartan HCTZ AN 32/25</i> (EA) .....	146
<i>Butamol 5</i> (QA) .....	26, 737	<i>Candesartan Sandoz</i> (SZ) .....	142
<i>Bydureon</i> (AP) .....	85	<i>Candesartan Sandoz</i> (SZ) .....	141
<i>Byetta 10 microgram</i> (AP) .....	87	<i>Candesartan/HCT Sandoz</i> (SZ) .....	145, 146
<i>Byetta 5 microgram</i> (AP) .....	87	CAPECITABINE .....	287
<i>Cabaser</i> (PF) .....	674	<i>Capecitabine Alphapharm</i> (AF) .....	287
CABERGOLINE		<i>Capecitabine AN</i> (EA) .....	287
GENITO URINARY SYSTEM AND SEX HORMONES		<i>Capecitabine AN</i> (EA) .....	287
.....	208	<i>Capecitabine Apotex</i> (TX) .....	287
NERVOUS SYSTEM .....	674	<i>Capecitabine MYX</i> (OC) .....	287
CADEXOMER-IODINE .....	1678	<i>Capecitabine Sandoz</i> (SZ) .....	287
<i>Cadivast 10/10</i> (AF) .....	190	<i>Capecitabine-DRLA</i> (RZ) .....	287
<i>Cadivast 10/20</i> (AF) .....	189	<i>Capoten</i> (RW) .....	131, 132
<i>Cadivast 10/40</i> (AF) .....	189	CAPTOPRIL .....	131, 132
<i>Cadivast 10/80</i> (AF) .....	189	<i>Captopril Sandoz</i> (SZ) .....	131, 132
<i>Cadivast 5/10</i> (AF) .....	189	<i>Carafate</i> (AS) .....	42
<i>Cadivast 5/20</i> (AF) .....	189	CARBAMAZEPINE .....	658, 659
<i>Cadivast 5/40</i> (AF) .....	189	<i>Carbamazepine Sandoz</i> (SZ) .....	659
<i>Cadivast 5/80</i> (AF) .....	190	CARBAMIDE PEROXIDE .....	1673
<i>Caduet 10/10</i> (PF) .....	190	<i>Carbimazol ARISTO</i> (PQ) .....	232
<i>Caduet 10/20</i> (PF) .....	189	CARBIMAZOLE .....	231
<i>Caduet 10/40</i> (PF) .....	189	<i>CarboFLEX 403202</i> (CC) .....	1679
<i>Caduet 10/80</i> (PF) .....	189	<i>CarboFLEX 403204</i> (CC) .....	1679
<i>Caduet 5/10</i> (PF) .....	189	<i>Carbohydrate Free Mixture</i> (SB) .....	823
<i>Caduet 5/20</i> (PF) .....	189	CARBOHYDRATE, FAT, VITAMINS, MINERALS AND	
<i>Caduet 5/40</i> (PF) .....	189	TRACE ELEMENTS .....	819
<i>Caduet 5/80</i> (PF) .....	190	CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE	
<i>Caelyx</i> (JC) .....	920, 1157	ELEMENTS AND SUPPLEMENTED WITH	
<i>Cal-500</i> (PP) .....	91, 1647	ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID	
<i>CAL-600</i> (PP) .....	1647, 1648	.....	819
CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE		CARBOMER-974 .....	772
.....	192, 193	CARBOMER-980 .....	773

carbzero(VF).....	789	CETRORELIX .....	1629
Cardasa(AF).....	1648	Cetrotide(SG).....	1629
Cardiprin 100(RC).....	1648	C-Flox 250 (AL).....	261
Cardizem CD(SW).....	131	C-Flox 500 (AL).....	260
Cardizem(SW).....	131	C-Flox 750 (AL).....	260
Cardol (AF).....	114, 115	Champix(PF).....	729, 730
CARMELLOSE SODIUM.....	773, 774, 775	Chem mart Alendronate Plus D3 70 mg/140 mcg (CH).....	625
CARMELLOSE SODIUM + GELATIN + PECTIN .....	1652	Chem mart Alendronate Plus D3 70 mg/140 mcg(CH).....	1664
CARMELLOSE SODIUM + GLYCEROL .....	775	Chem mart Alendronate Plus D3 70 mg/70 mcg (CH).....	626
CARMUSTINE.....	283	Chem mart Alendronate Plus D3 70 mg/70 mcg(CH).....	1664
Cartia(AS).....	1648	Chem mart Allopurinol(CH).....	619, 620
CARVEDILOL.....	127	Chem mart Amitriptyline(CH).....	701
Carvedilol AN (EA).....	127	Chem mart Amlodipine(CH).....	128
Carvedilol Sandoz(SZ).....	127	Chem mart Amoxicillin and Clavulanic Acid (CH).....	243, 244
Catapres 100 (BY).....	119	Chem mart Atenolol(CH).....	124
Catapres(BY).....	119	Chem mart Atorvastatin (CH).....	153, 154, 155
Caverject Impulse(PF).....	1658	Chem mart Azithromycin (CH).....	
Cavicare 4563(SN).....	1682	Repatriation Pharmaceutical Benefits Scheme.....	1661
Cavstat(AF).....	158, 159, 160, 161, 162, 163	Chem mart Azithromycin (CH).....	
Ceclor CD(AS).....	249	ANTIINFECTIVES FOR SYSTEMIC USE .....	254
Ceclor(AS).....	249	SENSORY ORGANS.....	750
CEFACLOR.....	249	Chem mart Bisoprolol (CH).....	124, 125
Cefaclor GH (GQ).....	249	Chem mart Candesartan (CH).....	141
Cefalexin Sandoz (SZ).....	245, 246, 247	Chem mart Candesartan HCTZ 16/12.5 (CH).....	145
Cefalexin Sandoz(SZ).....	246, 247	Chem mart Candesartan HCTZ 32/12.5 (CH).....	145
Cefazolin Sandoz(SZ).....	248, 249	Chem mart Candesartan HCTZ 32/25 (CH).....	146
Cefazolin-AFT(AE).....	247, 248	Chem mart Candesartan(CH).....	142
CEFEPIME.....	252	Chem mart Carvedilol 12.5 mg (CH).....	127
Cefepime Alphapharm (AF).....	252	Chem mart Carvedilol 25 mg (CH).....	127
Cefepime Kabi(PK).....	252	Chem mart Carvedilol 3.125 mg(CH).....	128
Cefepime-AFT(AE).....	252	Chem mart Carvedilol 6.25 mg (CH).....	127
CEFOTAXIME.....	250	Chem mart Celecoxib (CH).....	617
CEFTRIAZONE.....	251	Chem mart Citalopram(CH).....	703
Ceftriaxone Alphapharm(AF).....	251, 252	Chem mart Clarithromycin (CH).....	254
Ceftriaxone Sandoz (SZ).....	252	Chem mart Clindamycin(CH).....	257, 258
Ceftriaxone-AFT(AE).....	251, 252	Chem mart Clopidogrel(CH).....	98, 99, 1649
CEFUROXIME.....	249	Chem mart Clopidogrel/Aspirin 75/100 (CH).....	100
Celapram(AF).....	703	Chem mart Donepezil(CH).....	719, 720
Celaxib(AF).....	617	Chem mart Doxycycline (CH).....	233, 234, 235, 236
Celazadine (JU).....	919, 1156, 1157	Chem mart Doxycycline(CH).....	234
Celebrex (PF).....	617	Chem mart Duloxetine(CH).....	710
CELECOXIB.....	617	Chem mart Escitalopram(CH).....	704
Celecoxib AN(EA).....	617	Chem mart Fluoxetine (CH).....	706
Celecoxib GH (GQ).....	617	Chem mart Frusemide (CH).....	121
Celecoxib RBX(RA).....	617	Chem mart Gliclazide MR (CH).....	66
Celecoxib Sandoz (SZ).....	617	Chem mart Gliclazide(CH).....	66
Celestone Chronodose(MK).....	226, 227	Chem mart Hydroxychloroquine (CH).....	618
Celestone-M(MK).....	197	Chem mart Indapamide SR (CH).....	120
Celxi(RW).....	617	Chem mart Irbesartan (CH).....	142, 143
Celica (RA).....	703	Chem mart Irbesartan HCTZ (CH).....	146, 147
CellCept (RO).....	366, 367, 946, 1184, 1185	Chem mart Isosorbide Mononitrate(CH).....	117
CellCept(RO).....	367, 946, 1184	Chem mart Latanoprost (CH).....	761
Cellufresh(AG).....	774	Chem mart Lercanidipine(CH).....	129
Celluvisc(AG).....	774	Chem mart Letrozole (CH).....	352
Celsentri(VI).....	1336	Chem mart Lisinopril(CH).....	133
Cephalex 250(CR).....	245, 246, 247	Chem mart Meloxicam (CH).....	612, 613
Cephalex 500(CR).....	246, 247	Chem mart Meloxicam 15 mg (CH).....	612
CEPHALEXIN.....	245, 247	Chem mart Meloxicam 7.5 mg (CH).....	612
Cephalexin AN (EA).....	245, 246, 247	Chem mart Metformin (CH).....	65
Cephalexin generichealth(GQ).....	246, 247	Chem mart Metformin 1000 (CH).....	64
CEPHALOTHIN.....	247	Chem mart Metformin XR 1000(CH).....	65
CEPHAZOLIN.....	247, 248	Chem mart Metformin XR 500(CH).....	65
Cephazolin Alphapharm(AF).....	248	Chem mart Metoprolol (CH).....	126
Ceptolate(AF).....	366, 367, 946, 947, 1184, 1185	Chem mart Mirtazapine (CH).....	711
CERITINIB.....	293	Chem mart Montelukast(CH).....	748, 749
Certican(NV).....	365, 945, 1184	Chem mart Olanzapine (CH).....	681, 682, 683
CERTOLIZUMAB PEGOL.....	441, 442, 443, 446, 450, 451, 453, 456, 458	Chem mart Omeprazole (CH).....	38, 39
Cerumol(UN).....	1673	Chem mart Paroxetine (CH).....	707
CETIRIZINE.....	1671	Chem mart Perindopril(CH).....	134
		Chem mart Perindopril/ Indapamide 4/1.25(CH).....	138

Chem mart Pioglitazone(CH).....	79	Citrulline 1000(VF).....	820
Chem mart Pravastatin(CH).....	156, 157, 158	Citrulline Easy(OH).....	819
Chem mart Prazosin (CH).....	119	CITRULLINE WITH CARBOHYDRATE.....	819
Chem mart Quetiapine (CH).....	686, 687, 688	Clarac(ED).....	254
Chem mart Rabeprazole (CH).....	40, 41	Claratyne(BN).....	1672
Chem mart Ramipril (CH).....	135, 136, 137	Clarihexas (HX).....	254
Chem mart Ranitidine(CH).....	34	Clarithro 250(RW).....	254
Chem mart Rizatriptan (CH).....	654	CLARITHROMYCIN.....	254, 255, 912, 1149
Chem mart Rosuvastatin (CH) 158, 159, 160, 161, 162, 163		Clarithromycin AN (EA).....	254
Chem mart Roxithromycin(CH).....	256, 257	Clarithromycin Sandoz(SZ).....	254
Chem mart Sertraline(CH).....	707	Clavam 875 mg/125 mg(CR).....	243, 244
Chem mart Sildenafil (CH).....	1659	Cleocin (FZ).....	257, 258
Chem mart Simvastatin(CH).....	164, 165, 166	Clexane(SW).....	95, 96
Chem mart Sumatriptan (CH).....	655	Climara 100(BN).....	215
Chem mart Tramadol (CH).....	648, 649	Climara 25(BN).....	215
Chem mart Tramadol SR (CH).....	647, 648	Climara 50(BN).....	215
Chem mart Valaciclovir (CH).....	277, 278	Climara 75(BN).....	215
Chem mart Venlafaxine XR(CH).....	712, 713	CLINDAMYCIN.....	257
Chem mart Zopiclone (CH).....	1669	Clindamycin BNM(BZ).....	257, 258
Chemists' Own Laxative with Senna(RW).....	1644	Clindamycin-Link (LI).....	257, 258
Chemists' Own Macrogol with Electrolytes (RW).....	53, 830	Clindamyk(AF).....	257, 258
CHLORAMBUCIL.....	283	Clobemix (ED).....	708
CHLORAMPHENICOL.....	750	CLOBETASOL.....	205
CHLORHEXIDINE.....	1643	Clobex(GA).....	205
CHLORPROMAZINE.....	23, 677	CLODRONATE.....	621
Chlorsig(QA).....	750	Clofen 10 (AF).....	619
CHLORTHALIDONE.....	120	Clofen 25 (AF).....	619
Chlorvescent(AS).....	91	Clomid(SW).....	219
CHOLESTYRAMINE.....	167	CLOMIFENE.....	219
Cholstat 10(AF).....	156, 157	CLOMIPRAMINE.....	701
Cholstat 20 (AF).....	156, 157	Clonac 25 (RW).....	610, 611, 832
Cholstat 40 (AF).....	156, 158	Clonac 50 (RW).....	610, 611, 832
Cholvastin(RA).....	156, 157, 158	CLONAZEPAM.....	23, 657, 839
CHORIOGONADOTROPIN ALFA.....	1626	Clonea 3 Day Cream (AF).....	1657
Cialis(LY).....	1659	Clonea 6 Day Cream(AF).....	1658
CICLESONIDE.....	744	Clonea(AF).....	1651
Cifran(RA).....	260	CLONIDINE.....	119
Cilamox (QA).....	237, 238	CLOPIDOGREL.....	98, 1648
Cilamox(QA).....	237	CLOPIDOGREL + ASPIRIN.....	99
Cilicaine V(FM).....	240	Clopidogrel AN (EA).....	98, 99, 1649
Cilicaine VK(FM).....	239, 240	Clopidogrel GH (GQ).....	99
Cilicaine(QA).....	23, 241	Clopidogrel GH(GQ).....	1648
Cilopam-S (ER).....	704	Clopidogrel RBX(RA).....	99
CiloQuin(NM).....	751, 752	Clopidogrel Sandoz (SZ).....	99
Ciloxan(NV)		Clopidogrel Winthrop plus aspirin(WA).....	100
.SENSORY ORGANS.....	751, 752, 782	Clopidogrel Winthrop(WA).....	98, 99
CIMETIDINE.....	33	Clopidogrel/Aspirin Actavis 75/100(EA).....	100
Cimzia(UC).....	442, 443, 446, 449, 451, 453, 456, 458, 461	Clopidogrel/Aspirin Sandoz 75/100 (SZ).....	100
CIPLA IMATINIB ADULT(LR) 307, 308, 309, 310, 312, 314, 316, 317		Clopidogrel-DRLA(RZ).....	99
Cipramil(LU).....	703	Clopidogrel-GA(EA).....	98, 99
CIPROFLOXACIN		Clopine 100(PF).....	1053, 1292, 1339
.ANTIINFECTIVES FOR SYSTEMIC USE.....	260, 261	Clopine 200(PF).....	1053, 1292, 1339
.SENSORY ORGANS.....	751, 752, 782	Clopine 25(PF).....	1053, 1292, 1339
Ciprofloxacin AN (EA).....	260	Clopine 50(PF).....	1053, 1292, 1339
Ciprofloxacin Sandoz (SZ).....	260	Clopine Suspension(PF).....	1053, 1292, 1339
Ciprofloxacin Sandoz(SZ).....	261	Clopixol Depot(LU).....	680
Ciprofloxacin-BW(GQ).....	260	CLOSTRIDIUM BOTULINUM TYPE A TOXIN- HAEMAGGLUTININ COMPLEX.....	1344, 1345, 1346
Ciprol 250 (RW).....	261	CLOTTRIMAZOLE	
Ciprol 500(RW).....	260	.Repatriation Pharmaceutical Benefits Scheme.....	1651, 1657
Ciprol 750 (RW).....	261	Clovix 75 (RW).....	98
Ciproxin 250(BN).....	261	Clovix 75(RW).....	99
Ciproxin 500(BN).....	260	CLOZAPINE.....	1053, 1292, 1339
CITALOPRAM.....	703	Clozaril 100 (NV).....	1053, 1292, 1339
Citalopram Actavis (EA).....	703	Clozaril 25 (NV).....	1053, 1292, 1339
Citalopram Actavis (ED).....	703	COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR.....	1653
Citalopram AN(EA).....	703	COAL TAR SOLUTION + TAR + SALICYLIC ACID.....	1655
Citalopram AN(EF).....	703	Cobal-B12(JU).....	112
Citalopram Sandoz (SZ).....	703		
CITRULLINE.....	819		

Coban 1584(MM)	1675	Coversyl 5mg(SE)	134
Coban 2(MM)	1675	Coversyl Plus 5mg/1.25mg(SE)	138
COBIMETINIB	294	Coversyl Plus LD 2.5mg/0.625mg(SE)	138
Codalgin Forte (FM)	645, 646	Cozavan(AF)	143
Codapane Forte(AL)	645, 646	Creon 10,000(GO)	61
CODEINE		Creon 25,000(GO)	61
.NERVOUS SYSTEM	631	Creon 40,000(GO)	61
.RESPIRATORY SYSTEM	749	Creon Micro(GO)	61
Co-Diovan 160/12.5 (NV)	149	Crestor(AP)	158, 159, 160, 161, 162, 163
Co-Diovan 160/25 (NV)	149	.Crinone 8%(SG)	1626
Co-Diovan 320/12.5 (NV)	150	Crixivan 400 mg(MK)	1321
Co-Diovan 320/25 (NV)	150	CRIZOTINIB	294
Co-Diovan 80/12.5 (NV)	149	CROMOGLYCAT	
Cogentin(FK)	23, 671	.Repatriation Pharmaceutical Benefits Scheme	1670
Colaxsen (QA)	1644	.RESPIRATORY SYSTEM	746
Colazide(PK)	57	.SENSORY ORGANS	763
COLCHICINE	620	Crosuva 10 (ZP)	159, 160, 162, 163
Colese(AF)	1643	Crosuva 20 (ZP)	158, 159, 161, 162
Colgout(AS)	620	Crosuva 40 (ZP)	159, 160, 161, 163
Colifoam(HM)	57	Crosuva 5 (ZP)	158, 160, 161, 163
Colofac(GO)	1643	Crysanal(IY)	616, 833
Coloxyl 50(FM)	1644	Curam (SZ)	244, 245
Coloxyl with Senna(FM)	1644	Curam Duo (SZ)	243, 244
CombiDERM 651027(CC)	1686	Curam Duo 500/125 (SZ)	244, 245
CombiDERM 651031(CC)	1686	Curam Duo Forte 875/125 (SZ)	243, 244
Combigan(AG)	756	Curity 4112(KE)	1685
Combivir(VI)	1333	Cutifilm Plus 36361370(SN)	1681
Comfarol Forte (SZ)	645, 646	Cutifilm Plus 36361371(SN)	1681
Comfeel Plus Pressure Relieving 3350(CT)	1689	Cutilin Non-Stick Wound Pad 36361374(SN)	1693
Comfeel Plus Pressure Relieving 3353(CT)	1689	Cutilin Non-Stick Wound Pad 36361375(SN)	1692
Comfeel Plus Transparent 3530(CT)	1688	Cutinova Hydro 66047441(SN)	1687
Comfeel Plus Transparent 3533(CT)	1688	Cutinova Hydro 66047443(SN)	1687
Comfeel Plus Transparent 3536(CT)	1688	Cycloblastin(ZX)	283
Comfeel Plus Ulcer Dressing 3110(CT)	1689	CYCLOPHOSPHAMIDE	283
Comfeel Purilon Gel 3900(CT)	1691	CYCLOSPORIN	606, 1037, 1276
Comfeel SeaSorb Dressing 3705(CT)	1680	Cyclosporin Sandoz(SZ)	606, 607, 1038, 1277
Comfeel SeaSorb Dressing 3710(CT)	1680	Cyklokapron (PF)	110
Comfeel SeaSorb Filler 3740(CT)	1679	Cymbalta(LY)	710
Comprilan 01027-00(BV)	1674	Cymevene(RO)	912, 1150, 1319
Comtan(NV)	677	Cyprocur 100 (QA)	220, 349
Concerta(JC)	716, 717	Cyprocur 50 (QA)	220, 221, 349
Copaxone(TB)	357	CYPROHEPTADINE	656
CoPlavix (SW)	100	Cyprone 100(AF)	
Coralan(SE)	118	.ANTINEOPLASTIC AND IMMUNOMODULATING	
Corbeton 40(AF)	123	.AGENTS	349
Cardarone X 100 (SW)	114	.GENITO URINARY SYSTEM AND SEX HORMONES	
Cardarone X 200(SW)	114	.....	220
Cordilox 180 SR(GT)	130	Cyprone(AF)	
Cordilox SR(GT)	130	.ANTINEOPLASTIC AND IMMUNOMODULATING	
CORIFOLLITROPIN ALFA	1627	.AGENTS	349
Cortate(AS)	227	.GENITO URINARY SYSTEM AND SEX HORMONES	
Cortic-DS 1%(FM)	194	.....	220, 221
Cortic-DS 1%(QA)	1655	Cyprostat (SY)	
CORTISONE	227	.ANTINEOPLASTIC AND IMMUNOMODULATING	
Cortival 1/2(FM)	197, 198	.AGENTS	349
Cortival 1/5(FM)	197	.GENITO URINARY SYSTEM AND SEX HORMONES	
Cosamide 50 (AF)	348	.....	220, 221
Cosdor(QA)	758	Cyprostat-100 (SY)	
Co-Senna(PP)	1644	.ANTINEOPLASTIC AND IMMUNOMODULATING	
Cosentyx(NV)	556, 557, 559, 562, 565, 568, 571, 574, 579	.AGENTS	349
Cosopt(MF)	758	.GENITO URINARY SYSTEM AND SEX HORMONES	
Cosudex(AP)	348	.....	220
Cotellic(RO)	294	CYPROTERONE	
Coumadin(QA)	93	.ANTINEOPLASTIC AND IMMUNOMODULATING	
Coveram 10/10(SE)	139	.AGENTS	349
Coveram 10/5(SE)	140	.GENITO URINARY SYSTEM AND SEX HORMONES	
Coveram 5/10(SE)	140	.....	220
Coveram 5/5(SE)	140	Cyproterone AN(EA)	
Coversyl 10mg(SE)	134	.ANTINEOPLASTIC AND IMMUNOMODULATING	
Coversyl 2.5mg(SE)	133	.AGENTS	349

.GENITO URINARY SYSTEM AND SEX HORMONES		<i>Dermatane(ER)</i> .....	206
.....	220, 221	<i>Descovy(GI)</i> .....	1332
<i>Cyproterone Sandoz (HX)</i>		<i>Desfax(AF)</i> .....	709
.ANTINEOPLASTIC AND IMMUNOMODULATING		DEFERRIOXAMINE .....	1076, 1316
AGENTS .....	349	DESMOPRESSIN .....	224, 225
.GENITO URINARY SYSTEM AND SEX HORMONES		DESVEN (RW) .....	709
.....	220, 221	DESVENLAFAXINE .....	709
<i>Cyrotone(ER)</i>		<i>Desvenlafaxine Actavis(EA)</i> .....	709
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Desvenlafaxine GH XR (GQ)</i> .....	709
AGENTS .....	349	<i>Desvenlafaxine Sandoz (SZ)</i> .....	709
.GENITO URINARY SYSTEM AND SEX HORMONES		DEXAMETHASONE	
.....	220	.SENSORY ORGANS .....	752
<i>Cystadane(EU)</i> .....	92	.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
<i>Cystine 500(VF)</i> .....	820	HORMONES AND INSULINS .....	227
CYSTINE WITH CARBOHYDRATE .....	820	<i>Dexamethasone Mylan(AF)</i> .....	24, 227
DABIGATRAN .....	102, 103, 104	DEXAMETHASONE SODIUM PHOSPHATE .....	24, 227
DABRAFENIB .....	295	DEXAMFETAMINE .....	716
DACLATASVIR .....	278, 279, 914, 1151, 1152	<i>Dexamethsone(AS)</i> .....	227
DACLIZUMAB .....	543	DEXTRAN-70 + HYPROMELLOSE .....	775, 776
<i>Daivobet (LO)</i> .....	193	<i>Diabex 1000(AL)</i> .....	64
<i>Daivobet 50/500 gel(LO)</i> .....	193	<i>Diabex 850(AL)</i> .....	65
<i>Daklinza(BQ)</i> .....	279, 914, 1152	<i>Diabex XR 1000(AL)</i> .....	65
<i>Daktarin Tincture(JT)</i> .....	191	<i>Diabex XR(AL)</i> .....	65
<i>Daktarin(JT)</i> .....	190, 191	<i>Diabex(AL)</i> .....	65
<i>Dalacin C(PF)</i> .....	257, 258	<i>Diaformin 1000(AF)</i> .....	64
DALTEPARIN SODIUM .....	93, 94	<i>Diaformin 850(AF)</i> .....	65
DANAZOL .....	221	<i>Diaformin XR (AF)</i> .....	65
<i>Dantrium(PF)</i> .....	619	<i>Diaformin XR 1000 (AF)</i> .....	65
DANTROLENE .....	619	<i>Diaformin(AF)</i> .....	65
<i>Daonil(SW)</i> .....	66	<i>Dialamine(SB)</i> .....	820
DAPAGLIFLOZIN .....	87	<i>Diamicron 60mg MR(SE)</i> .....	66
DAPAGLIFLOZIN + METFORMIN .....	68	<i>Diamox(RW)</i> .....	756
<i>Dapa-Tabs(AF)</i> .....	120	<i>Diapride 1(RW)</i> .....	67
DAPSONE		<i>Diapride 2(RW)</i> .....	66
.ANTIINFECTIVES FOR SYSTEMIC USE .....	271	<i>Diapride 3(RW)</i> .....	66
.DERMATOLOGICALS .....	207	<i>Diapride 4(RW)</i> .....	66
<i>Daraprim(RW)</i> .....	733	<i>Diasp SR (RW)</i> .....	101
DARBEPOETIN ALFA .....	850, 1087	<i>Diastix(BN)</i> .....	787
DARUNAVIR .....	1320, 1321	DIAZEPAM .....	24, 697, 698, 840
DARUNAVIR + COBICISTAT .....	1331	<i>Diazepam Elixir(ON)</i> .....	697
<i>Darunavir Mylan(AF)</i> .....	1320, 1321	<i>Dibenyline(GH)</i>	
DASATINIB .....	296, 298, 300	.CARDIOVASCULAR SYSTEM .....	123
<i>DBL Cefepime (PF)</i> .....	252	.GENITO URINARY SYSTEM AND SEX HORMONES	
<i>DBL Zoledronic Acid (PF)</i> .....	1052, 1291	.....	223
<i>DBL Zoledronic Acid(PF)</i> .....	1052, 1291	<i>Dibenzyliline(BZ)</i>	
<i>Deca-Durabolin(AS)</i> .....	92	.CARDIOVASCULAR SYSTEM .....	123
<i>Decapeptyl(FP)</i> .....	1630	.GENITO URINARY SYSTEM AND SEX HORMONES	
DEFERASIROX .....	1076, 1315	.....	223
DEFERIPRONE .....	1076, 1315	<i>Dicarz(AF)</i> .....	127
DEGARELIX .....	353	DICHLOROBENZENE WITH CHLORBUTOL AND	
<i>Delucon 100(DO)</i> .....	686	ARACHIS OIL .....	1673
<i>Delucon 200(DO)</i> .....	686	DICLOFENAC	
<i>Delucon 25(DO)</i> .....	688	.MUSCULO-SKELETAL SYSTEM .....	610, 611
<i>Delucon 300(DO)</i> .....	687	.Palliative Care .....	831
DENOSUMAB .....	629	.Repatriation Pharmaceutical Benefits Scheme .....	1656
<i>Denpax(AF)</i> .....	641, 642, 643, 644	<i>Diclofenac Amneal(ED)</i> .....	610, 611, 832
<i>Densate 70 (DO)</i> .....	621	<i>Diclofenac AN (EA)</i> .....	610, 611, 832
<i>Depo-Medrol(PF)</i> .....	228, 229	<i>Diclofenac Sandoz(SZ)</i> .....	610, 611, 832
<i>Depo-Nisolone(FZ)</i> .....	228, 229	DICLOXACILLIN .....	241
<i>Depo-Provera(PF)</i> .....	211	DIDANOSINE .....	1323
<i>Depo-Ralovera(FZ)</i> .....	211	<i>Diffiam(LA)</i> .....	33, 829
<i>Depreta 30 (DO)</i> .....	710	<i>Diffucan (PF)</i> .....	265
<i>Depreta 60 (DO)</i> .....	710	<i>Diffucan(PF)</i> .....	266, 267
<i>Deptran 10(AF)</i> .....	702	DIGOXIN .....	113
<i>Deptran 25(AF)</i> .....	702	<i>Dilantin Infatabs(PF)</i> .....	657
<i>Deptran 50(AF)</i> .....	702	<i>Dilantin Sodium(PF)</i> .....	657
<i>Deralin 10(AF)</i> .....	123	<i>Dilantin(PF)</i> .....	657
<i>Deralin 160(AF)</i> .....	123	<i>Dilart (AF)</i> .....	144
<i>Deralin 40(AF)</i> .....	124	<i>Dilart HCT 160/12.5(AF)</i> .....	149
<i>Dermatane (ER)</i> .....	205, 206	<i>Dilart HCT 160/25(AF)</i> .....	149

<i>Dilart HCT 320/12.5(AF)</i> .....	150	<i>Doxycycline AN(EA)</i> .....	234, 236
<i>Dilart HCT 320/25(AF)</i> .....	150	<i>Doxycycline Sandoz (HX)</i> .....	234
<i>Dilart HCT 80/12.5(AF)</i> .....	149	<i>Doxycycline Sandoz(HX)</i> .....	233, 234, 235, 236
<i>Dilatrend 12.5 (PB)</i> .....	127	<i>Doxylin 100 (AF)</i> .....	234
<i>Dilatrend 25 (PB)</i> .....	127	<i>Doxylin 100(AF)</i> .....	233, 234, 235
<i>Dilatrend 6.25 (PB)</i> .....	127	<i>Doxylin 50 (AF)</i> .....	236
<i>Dilaudid(MF)</i> .....	631, 632	<i>D-Penaminate(AL)</i> .....	619
<i>Dilaudid-HP(MF)</i> .....	631	DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND .....	1679
DILTIAZEM .....	131	DRESSING ALGINATE CAVITY WOUND .....	1679
<i>Diltiazem Actavis(ED)</i> .....	131	DRESSING ALGINATE SUPERFICIAL WOUND .....	1679, 1680
<i>Diltiazem AN (EA)</i> .....	131	DRESSING ALGINATE WITH MANUKA HONEY .....	1680
<i>Diltiazem Sandoz CD(SZ)</i> .....	131	DRESSING FILM .....	1681
<i>Diltiazem Sandoz(SZ)</i> .....	131	DRESSING FILM ISLAND .....	1681
DIMETHICONE-350 + GLYCEROL .....	1652	DRESSING FOAM HEAVY EXUDATE .....	1681
DIMETHYL FUMARATE .....	731	DRESSING FOAM MODERATE EXUDATE .....	1682
<i>Dimirel (AV)</i> .....	66, 67	DRESSING FOAM WITH SILICONE .....	1682
<i>Diovan(NV)</i> .....	144, 145	DRESSING FOAM WITH SILICONE AND SILVER .....	1682
<i>Dipentum(IX)</i> .....	60	DRESSING FOAM WITH SILICONE HEAVY EXUDATE .....	1683
DIPHENOXYLATE + ATROPINE SULFATE .....	56	DRESSING FOAM WITH SILICONE LIGHT EXUDATE .....	1683
<i>Diphereline(IS)</i> .....	347	DRESSING FOAM WITH SILICONE MODERATE EXUDATE .....	1684
DIPHThERIA TOXOID + TETANUS TOXOID .....	24, 283	DRESSING FOAM WITH SILVER .....	1684
<i>Diprosone(MK)</i> .....	195, 196, 197	DRESSING GAUZE ABSORBENT .....	1685
DIPYRIDAMOLE .....	100	DRESSING GAUZE EYE .....	1685
DIPYRIDAMOLE + ASPIRIN .....	100	DRESSING GAUZE PARAFFIN .....	1685
DISOPYRAMIDE .....	113	DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE .....	1685
<i>Distaph 250(AF)</i> .....	241	DRESSING HYDROACTIVE DEBRIDEMENT .....	1685
<i>Distaph 500(AF)</i> .....	241	DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM .....	1686
<i>Dithiazide(PL)</i> .....	120	DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE .....	1687
<i>Ditropan(SW)</i> .....	222	DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE .....	1687
<i>Dizole 100 (AF)</i> .....	266	DRESSING HYDROCOLLOID CAVITY WOUND .....	1687
<i>Dizole 200(AF)</i> .....	265	DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE .....	1687, 1688
<i>Dizole 50(AF)</i> .....	266	DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE .....	1688, 1689
<i>docomega(VF)</i> .....	820	DRESSING HYDROFIBRE ALTERNATE TO ALGINATES .....	1689
DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE	820	DRESSING HYDROFIBRE GELLING FIBRE .....	1690
DOCUSATE .....		DRESSING HYDROFIBRE WITH SILVER .....	1690
Repatriation Pharmaceutical Benefits Scheme .....	1644, 1673	DRESSING HYDROGEL .....	1690
DOCUSATE + SENNOSIDE B .....	1644	DRESSING HYDROGEL AMORPHOUS .....	1690, 1691
DOCUSATE + SENNOSIDES .....	1644	DRESSING HYDROGEL FOAM .....	1691
<i>Dolapril 0.5(RW)</i> .....	137	DRESSING HYDROGEL RIBBON .....	1691
<i>Dolapril 1(RW)</i> .....	137	DRESSING HYDROGEL SHEET .....	1692
<i>Dolapril 2(RW)</i> .....	137	DRESSING NON ADHERENT .....	1692
<i>Dolapril 4(RW)</i> .....	137	DRESSING TULLE NON GAUZE PARAFFIN .....	1693
DOLUTEGRAVIR .....	1335	DRESSING WITH SILVER .....	1693
DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE .....	1331	<i>Drixine(BN)</i> .....	1670
DOMPERIDONE .....	42	<i>Dronalen Plus D-Cal(AF)</i> .....	627
DONEPEZIL .....	718, 719	<i>Dronalen Plus(AL)</i> .....	625
<i>Donepezil AN (EA)</i> .....	719, 720	DRY PSYLLIUM HUSK .....	1645
<i>Donepezil generichealth(GQ)</i> .....	719, 720, 721	<i>Dulcolax(VZ)</i> .....	52, 830, 1644
<i>Donepezil RBX (RA)</i> .....	719, 721	DULOXETINE .....	709
<i>Donepezil Sandoz (SZ)</i> .....	719, 720	<i>Duloxetine AN(EA)</i> .....	710
<i>Donepezil Sandoz(SZ)</i> .....	719, 721	<i>Duloxetine GH (GQ)</i> .....	710
<i>Donepezil-DRLA(RZ)</i> .....	719, 720	<i>Duocal(SB)</i> .....	824
<i>Donepezil-GA (ED)</i> .....	719, 720	<i>DuoCover(AV)</i> .....	100
DORNASE ALFA .....	1070, 1309	<i>Duodart 500ug/400ug(GK)</i> .....	223, 1660
<i>Doryx(YN)</i> .....	234, 235, 236	<i>DuoDERM CGF H7660(CC)</i> .....	1688
DORZOLAMIDE .....	758	<i>DuoDERM CGF H7662(CC)</i> .....	1688
DORZOLAMIDE + TIMOLOL .....	758	<i>DuoDERM Extra Thin H7955(CC)</i> .....	1687
<i>Dorzolamide/Timolol Sandoz 20/5(EA)</i> .....	758		
<i>Dorzolamide/Timolol Sandoz 20/5(SZ)</i> .....	758		
<i>Dostinex (PF)</i> .....	208, 209		
<i>Dothep 25(AF)</i> .....	702		
<i>Dothep 75(AF)</i> .....	702		
DOTHIEPIN .....	702		
DOXEPIN .....	702		
DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL .....	920, 1157		
<i>Doxsig(RW)</i> .....	233, 234, 235		
DOXYCYCLINE .....	233, 234, 235, 236		
<i>Doxycycline AN (EA)</i> .....	233, 234, 235		

DuoDERM Gel H7987(CC)	1691	ELTROMBOPAG	844, 1081
DuoDERM Gel H7990(CC)	1691	Emend IV(MK)	49
DuoDERM Paste H7930(CC)	1687	Emend(MK)	48
Duodopa(VE)	672, 1052, 1291	EMEXLON (RW)	42
Duofilm Solution(GK)	1656	EMPAGLIFLOZIN	88
DuoPlidogrel (GZ)	100	EMPAGLIFLOZIN + METFORMIN	69, 70
Duotrav(NV)	762	EMTRICITABINE	1324
Durafiber 66800560(SN)	1690	EMTRICITABINE + RILPIVIRINE + TENOFOVIR	
Durafiber 66800561(SN)	1690	ALAFENAMIDE	1332
Durafiber 66800563(SN)	1690	EMTRICITABINE + TENOFOVIR ALAFENAMIDE	1332
Duride (AF)	117	Emtriva(GI)	1324
Durogesic 100 (JC)	644	E-Mycin 200(AF)	255
Durogesic 12 (JC)	642	E-Mycin 400(AF)	256
Durogesic 25 (JC)	642	E-Mycin(AF)	255, 256
Durogesic 50 (JC)	643	ENALAPRIL	132
Durogesic 75 (JC)	643	ENALAPRIL + HYDROCHLOROTHIAZIDE	137
Duro-K(NM)	91	Enalapril Actavis(ED)	132
Duro-Tuss(IA)	1671	Enalapril generichealth (GQ)	132
DUTASTERIDE	223, 1660	Enalapril Sandoz(SZ)	132
DUTASTERIDE + TAMSULOSIN	223, 1660	Enalapril/HCT Sandoz(SZ)	137
Dutran 100(EA)	644	Enbrel (PF)	486, 488, 490, 498, 501, 505, 508, 525
Dutran 12(EA)	642	Enbrel(PF)	471, 473, 475, 476, 478, 483, 486, 488, 490, 493, 494, 498, 501, 505, 508, 519, 525, 970, 1209
Dutran 25(EA)	642	Endep 10(AF)	701
Dutran 50(EA)	643	Endep 25(AF)	701
Dutran 75(EA)	643	Endep 50(AF)	701
Dysport(IS)	1345, 1346	Endometrin(FP)	1626
DYTREX 30(RW)	710	Endone(QA)	638, 639
DYTREX 60(RW)	710	Endoxan(BX)	283
E.E.S. 200(GH)	255, 256	Energivit(SB)	819
E.E.S. Granules(GH)	256	ENFUVIRTIDE	1335
EAA Supplement(VF)	820	Enidin(PE)	755
Ear Clear for Ear Wax Removal(KY)	1673	Enlafax-XR (AF)	712, 713
Easiphen(SB)	814	ENOXAPARIN SODIUM	95
Ebixa (LU)	725, 726	Enstilar(LO)	193
ECULIZUMAB	937, 939, 941, 1176, 1178, 1179	ENTAC (LR)	1324, 1325
Edecrin(FK)	121	ENTACAPONE	677
Edronax(PF)	712	ENTECAVIR	1324, 1325
Edurant(JC)	1330	Entecavir Amneal(EA)	1324, 1325
EFAVIRENZ	1328	Entecavir APOTEX (TX)	1324, 1325
Efexor-XR (PF)	712, 713	Entecavir GH(GQ)	1324, 1325
Efexor-XR(PF)	712	Entecavir Mylan (AF)	1324, 1325
Effient(LY)	101	ENTECAVIR RBX(RA)	1324, 1325
EFORMOTEROL	736	Entecavir Sandoz (SZ)	1324, 1325
Efudix (IA)	1662	ENTECLUDE(RW)	1324, 1325
Egoderm Cream(EO)	1656	Entresto(NV)	153
Egoderm Ointment(EO)	1656	ENTRIP (RW)	701
Egopsoryl-TA(EO)	1653	Entyvio(TK)	952, 957, 1190, 1196
Elastoplast 2225(BE)	1676	ENZALUTAMIDE	349
Elastoplast 2226(BE)	1676	Epclusa(GI)	282, 917, 1155
Elastoplast 2227(BE)	1676	Epiduo(GA)	205
Elaxine SR 150(ZP)	712	Epilim EC(SW)	661
Elaxine SR 37.5 (ZP)	712	Epilim Liquid(SW)	661
Elaxine SR 75(ZP)	713	Epilim Syrup(SW)	661
Eldepryl(AS)	677	Epilim(SW)	660
Eleanor 150/30 ED(EA)	210	EpiPen Jr.(AL)	
EleCare LCP(AB)	793, 794	CARDIOVASCULAR SYSTEM	116
EleCare(AB)	790, 791, 792	RESPIRATORY SYSTEM	747
ELETRIPTAN	653	EpiPen(AL)	
Eleuphrat(FR)	195, 196, 197	CARDIOVASCULAR SYSTEM	116
Eleva 100 (AF)	707, 708	RESPIRATORY SYSTEM	747
Eleva 50 (AF)	707, 708	Epiramax 100 (RW)	668
Elidel(HM)	206	Epiramax 200 (RW)	668
Eligard 1 month(TL)	345	Epiramax 25 (RW)	669
Eligard 3 month(TL)	345	Epiramax 50 (RW)	669
Eligard 4 month(TL)	345	EPLERENONE	122
Eligard 6 month(TL)	345	Eplerenone AN(EA)	122
Elquis(BQ)	104, 105, 106, 107	EPOETIN ALFA	851, 1088
Elocon Alcohol Free(MK)	202, 203, 204	EPOETIN BETA	852, 1089
Elocon(MK)	202, 203, 204, 1655	EPOETIN LAMBDA	852, 1089
Elonva(MK)	1627		

EPOPROSTENOL .....	870, 1107	EUCALYPTUS OIL + MENTHOL + METHYL SALICYLATE .....	1662
<i>Eprex 1000(JC)</i> .....	851, 1088	<i>Eucerin(BE)</i> .....	1652
<i>Eprex 10000(JC)</i> .....	851, 1088	<i>Eutroxsig(FM)</i> .....	231
<i>Eprex 20,000(JC)</i> .....	851, 1088	<i>Evelyn 150/30 ED (GQ)</i> .....	210
<i>Eprex 2000(JC)</i> .....	851, 1088	EVEROLIMUS	
<i>Eprex 3000(JC)</i> .....	851, 1088	ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Eprex 40,000(JC)</i> .....	851, 1088	AGENTS .....	302, 303, 304, 364
<i>Eprex 4000(JC)</i> .....	851, 1088	.Highly Specialised Drugs Program (Private Hospital)	945
<i>Eprex 5000(JC)</i> .....	851, 1088	.Highly Specialised Drugs Program (Public Hospital)	1183
<i>Eprex 6000(JC)</i> .....	851, 1088	<i>Evifyne (EL)</i> .....	630
<i>Eprex 8000(JC)</i> .....	852, 1089	<i>Eviplera(GI)</i> .....	1335
EPROSARTAN .....	142	<i>Evista(LY)</i> .....	630
EPROSARTAN + HYDROCHLOROTHIAZIDE .....	146	EVOLOCUMAB .....	167, 168
EPTIFIBATIDE .....	101	<i>Evotaz(BQ)</i> .....	1320
<i>Erivedge(RO)</i> .....	342	<i>Exaccord(RA)</i> .....	352
ERLOTINIB .....	301	<i>Exelon Patch 10(NV)</i> .....	724, 725
<i>Eryc(YN)</i> .....	255	<i>Exelon Patch 15(NV)</i> .....	723, 724
ERYTHROMYCIN .....	255	<i>Exelon Patch 5(NV)</i> .....	723, 724
ERYTHROMYCIN ETHYLSUCCINATE .....	255, 256	<i>Exelon(NV)</i> .....	723, 725
<i>Esbriet(RO)</i> .....	610	EXEMESTANE .....	351, 352
<i>Escicor 10(RA)</i> .....	704	<i>Exemestane AN (EA)</i> .....	352
<i>Escicor 20(RA)</i> .....	704	<i>Exemestane GH(GQ)</i> .....	352
ESCITALOPRAM .....	704, 705	<i>Exemestane Sandoz (SZ)</i> .....	352
<i>Escitalopram AN (EA)</i> .....	704	EXENATIDE .....	85, 86
<i>Escitalopram generichealth (GQ)</i> .....	704	<i>Exforge 10/160(NV)</i> .....	150
<i>Escitalopram Sandoz(HX)</i> .....	704	<i>Exforge 10/320(NV)</i> .....	150
<i>Escitalopram-DRLA(RZ)</i> .....	704	<i>Exforge 5/160(NV)</i> .....	150
<i>Esipram (CF)</i> .....	704	<i>Exforge 5/320(NV)</i> .....	150
<i>Esipram(CF)</i> .....	705	<i>Exforge 5/80(NV)</i> .....	150
<i>Esitalo(SZ)</i> .....	704	<i>Exforge HCT 10/160/12.5(NV)</i> .....	152
<i>Eskazole(AS)</i> .....	734	<i>Exforge HCT 10/160/25(NV)</i> .....	152
ESOMEPRAZOLE .....	35, 36	<i>Exforge HCT 10/320/25(NV)</i> .....	151
ESOMEPRAZOLE (&) CLARITHROMYCIN (&)		<i>Exforge HCT 5/160/12.5(NV)</i> .....	152
AMOXICILLIN .....	41	<i>Exforge HCT 5/160/25(NV)</i> .....	152
<i>Esomeprazole ACTAVIS(EA)</i> .....	35, 36, 37	<i>Exjade(NV)</i> .....	1076, 1315
<i>Esomeprazole Apotex(TX)</i> .....	35, 36	<i>Exorex(GN)</i> .....	192
<i>Esomeprazole GH (GQ)</i> .....	35, 36	<i>Extime 20(RW)</i> .....	707
<i>Esomeprazole GxP(AF)</i> .....	35, 36	<i>Eylea(BN)</i> .....	764, 766
<i>Esomeprazole RBX (RA)</i> .....	35, 36	EZETIMIBE .....	170
ESOMEPRAZOLE SANDOZ Hp7(SZ) .....	41	EZETIMIBE + ATORVASTATIN .....	173, 175
<i>Esomeprazole Sandoz(SZ)</i> .....	35, 36	EZETIMIBE + SIMVASTATIN .....	178, 180
ESPLER (RW) .....	122	<i>Ezetrol(MK)</i> .....	173
<i>Essential Amino Acid Mix(SB)</i> .....	820	<i>Ezovir (AF)</i> .....	274
ESSENTIAL AMINO ACIDS FORMULA .....	820	<i>Ezovir(AF)</i> .....	274, 275, 276
ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS		FAMCICLOVIR .....	274, 275
AND VITAMIN C .....	820	<i>Famciclovir AN (EA)</i> .....	274, 275, 276
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS		<i>Famciclovir AN(EA)</i> .....	274, 275
AND MINERALS .....	820	<i>Famciclovir FBM(FO)</i> .....	274
<i>Estalis continuous 50/140(SZ)</i> .....	217	<i>Famciclovir generichealth 250 (GQ)</i> .....	275
<i>Estalis continuous 50/250(SZ)</i> .....	217	<i>Famciclovir generichealth 250(GQ)</i> .....	274
<i>Estalis sequi 50/140(SZ)</i> .....	217	<i>Famciclovir generichealth 500 (GQ)</i> .....	276
<i>Estalis sequi 50/250(SZ)</i> .....	217	<i>Famciclovir Sandoz (SZ)</i> .....	274, 275
<i>Estamane (JU)</i> .....	352	<i>Famciclovir Sandoz(SZ)</i> .....	274, 275, 276
<i>Estraderm MX 100(JU)</i> .....	215	<i>Famciclovir SCP 250 (CR)</i> .....	275
<i>Estraderm MX 25(JU)</i> .....	215	<i>Famciclovir SCP 250(CR)</i> .....	274
<i>Estraderm MX 50(JU)</i> .....	215	<i>Famciclovir-GA (ED)</i> .....	274
<i>Estradot 100(SZ)</i> .....	215	<i>Famciclovir-GA(ED)</i> .....	274, 275, 276
<i>Estradot 25(SZ)</i> .....	215	<i>Famlo (RA)</i> .....	274
<i>Estradot 37.5(SZ)</i> .....	215	<i>Famlo(RA)</i> .....	275
<i>Estradot 50(SZ)</i> .....	215	FAMOTIDINE .....	33
<i>Estradot 75(SZ)</i> .....	215	<i>Famotidine AN (EA)</i> .....	33, 34
ETANERCEPT461, 463, 465, 466, 469, 471, 473, 476, 478,		<i>Famotidine Sandoz(SZ)</i> .....	33, 34
483, 486, 488, 490, 494, 498, 501, 505, 508, 519, 964,		<i>Famvir (HX)</i> .....	274, 275, 276
1203		<i>Famvir(HX)</i> .....	274, 275
ETHACRYNIC ACID .....	121	<i>Fareston(AS)</i> .....	348
ETHOSUXIMIDE .....	657	<i>Fasigyn(PF)</i> .....	265
ETONOGESTREL .....	210	<i>Faverin 100 (RW)</i> .....	706
ETOPOSIDE .....	288	<i>Faverin 50 (RW)</i> .....	706
ETRAVIRINE .....	1329	<i>Favic 125(RW)</i> .....	274

<i>Favic 250 (RW)</i> .....	274	<i>Flagyl S(SW)</i> .....	263
<i>Favic 250(RW)</i> .....	274, 275	<i>Flagyl(SW)</i> .....	263, 264
<i>Favic 500 (RW)</i> .....	275	<i>Flamazone(SN)</i> .....	194
<i>Favic 500(RW)</i> .....	276	<i>Flarex(NV)</i> .....	754
<i>Fawns and McAllan Proprietary Limited(FM)</i>		<b>FLECAINIDE</b> .....	114
<i>NERVOUS SYSTEM</i> .....	631, 656	<i>Flecainide Sandoz(SZ)</i> .....	114
<i>RESPIRATORY SYSTEM</i> .....	749	<i>Flecatub (AF)</i> .....	114
<i>Febridol (EA)</i> .....	650, 651, 1666	<i>Flexidress 650941(CC)</i> .....	1678
<b>FEBUXOSTAT</b> .....	620	<i>Flixotide Accuhaler(GK)</i> .....	744
<i>Feldene(PF)</i> .....	613, 614	<i>Flixotide Junior Accuhaler(GK)</i> .....	744
<i>Feldene-D(PF)</i> .....	613	<i>Flixotide Junior(GK)</i> .....	744
<i>Felodil XR 10(RW)</i> .....	129	<i>Flixotide(GK)</i> .....	744
<i>Felodil XR 5(RW)</i> .....	129	<i>Flolan(GK)</i> .....	873, 1110
<b>FELODIPINE</b> .....	129	<i>Flomaxtra(LS)</i> .....	1660
<i>Felodur ER 10 mg (TX)</i> .....	129	<i>Flopen (AS)</i> .....	242, 243
<i>Felodur ER 2.5 mg(TX)</i> .....	129	<i>Florinef(QA)</i> .....	226
<i>Felodur ER 5 mg (TX)</i> .....	129	<i>Fluanxol Concentrated Depot(LU)</i> .....	680
<i>Femara 2.5 mg(NV)</i> .....	352	<i>Fluanxol Depot(LU)</i> .....	680
<i>Femme-Tab ED 20/100(AE)</i> .....	209	<i>Flucil(AS)</i> .....	241
<i>Femme-Tab ED 30/150(AE)</i> .....	210	<i>Flucil(LN)</i> .....	242, 243
<i>Femolet (AF)</i> .....	352	<b>FLUCLOXACILLIN</b> .....	241, 242, 243
<i>Femoston 1/10(GO)</i> .....	217	<i>Flucon(NV)</i> .....	754
<i>Femoston 2/10(GO)</i> .....	217	<b>FLUCONAZOLE</b> .....	265, 266, 267
<i>Femoston-Conti(GO)</i> .....	217	<i>Fluconazole Alphapharm(AF)</i> .....	266, 267
<i>Fenac (AF)</i> .....	610, 611, 832	<i>Fluconazole Sandoz (SZ)</i> .....	265, 266
<i>Fenac 25 (AF)</i> .....	610, 611, 832	<i>Fluconazole Sandoz(SZ)</i> .....	266, 267
<i>Fendex ER (AF)</i> .....	129	<i>Fludara(GZ)</i> .....	287
<i>Fendex ER(AF)</i> .....	129	<b>FLUDARABINE</b> .....	287
<b>FENOFIBRATE</b> .....	166	<b>FLUDROCORTISONE ACETATE</b> .....	226
<i>Fenpatch 100 (ZP)</i> .....	644	<b>FLUNITRAZEPAM</b> .....	1668
<i>Fenpatch 12 (ZP)</i> .....	642	<b>FLUOROMETHOLONE</b> .....	754
<i>Fenpatch 25 (ZP)</i> .....	642	<b>FLUOROMETHOLONE ACETATE</b> .....	754
<i>Fenpatch 50 (ZP)</i> .....	643	<b>FLUOROURACIL</b> .....	1662
<i>Fenpatch 75 (ZP)</i> .....	643	<i>FLUOTEX(RF)</i> .....	706
<b>FENTANYL</b> .....	641, 642, 643, 834, 835, 836, 837	<b>FLUOXETINE</b> .....	706
<i>Fentanyl Sandoz(SZ)</i> .....	642, 643, 644	<i>Fluoxetine AN (EA)</i> .....	706
<i>Fentora(TB)</i> .....	835, 837	<i>Fluoxetine generichealth (GQ)</i> .....	706
<i>Fera(QA)</i> .....	352	<i>Fluoxetine Sandoz(SZ)</i> .....	706
<i>ferinject(VL)</i> .....	110	<i>Fluoxetine-GA(ED)</i> .....	706
<b>FERRIC PYROPHOSPHATE + THIAMINE + PYRIDOXINE</b> + <b>CYANOCOBALAMIN + LYSINE</b> .....	1647	<b>FLUPENTHIXOL DECANOATE</b> .....	680
<i>Ferriprox(TX)</i> .....	1076, 1315, 1316	<b>FLUTAMIDE</b> .....	350
<i>Ferro-f-tab(AE)</i> .....	111, 1649	<i>Flutamide MYLAN(AF)</i> .....	350
<i>Ferro-Liquid(AE)</i> .....	110	<i>Flutamin(AF)</i> .....	350
<i>Ferrosig(SI)</i> .....	110, 111	<b>FLUTICASONE</b> .....	744
<i>Ferro-tab(AE)</i> .....	110, 1649	<b>FLUTICASONE + EFORMOTEROL</b> .....	739
<b>FERROUS FUMARATE</b> .....	110, 1649	<b>FLUTICASONE + SALMETEROL</b> .....	740
<b>FERROUS FUMARATE + FOLIC ACID</b> .....	111, 1649	<i>Fluticasone + Salmeterol Cipla 125/25(LR)</i> .....	740
<b>FERROUS SULFATE</b> .....	110	<i>Fluticasone + Salmeterol Cipla 250/25(LR)</i> .....	741
<i>Fexal(SZ)</i> .....	1672	<i>Fluticasone Cipla Inhaler (LR)</i> .....	744
<b>FEXOFENADINE</b> .....	1672	<b>FLUTICASONE FUROATE + VILANTEROL</b> .....	741
<i>Fibre Health Natural Granular(PP)</i> .....	1645	<i>flutiform 125/5(MF)</i> .....	740
<i>Fibsol 10 (RW)</i> .....	133	<i>flutiform 250/10(MF)</i> .....	740
<i>Fibsol 20 (RW)</i> .....	133	<i>flutiform 50/5(MF)</i> .....	740
<i>Fibsol 5 (RW)</i> .....	133	<b>FLUVASTATIN</b> .....	155, 156
<b>FILGRASTIM</b> .....	921, 1159	<b>FLUVOXAMINE</b> .....	706
<i>Finasta (SZ)</i> .....	1661	<i>Fluvoxamine AN(ED)</i> .....	706
<b>FINASTERIDE</b> .....	1661	<i>Fluvoxamine GA (EA)</i> .....	706
<i>Finasteride Alphapharm(AF)</i> .....	1661	<i>Fluzole 200(RW)</i> .....	265
<i>Finasteride AN (EA)</i> .....	1661	<i>FML Liquifilm (AG)</i> .....	754
<i>Finasteride GH 5(GQ)</i> .....	1661	<b>FOLIC ACID</b> .....	112, 1650
<i>Finasteride-GA 5 (GN)</i> .....	1661	<b>FOLINIC ACID</b> .....	785, 786
<b>FINGOLIMOD</b> .....	365	<b>FOLLITROPIN ALFA</b> .....	217, 1627
<i>Finide (AL)</i> .....	1661	<b>FOLLITROPIN ALFA + LUTROPIN ALFA</b> .....	1628
<i>Finnacar(RW)</i> .....	1661	<b>FOLLITROPIN BETA</b> .....	218, 1628
<i>Finpro(RZ)</i> .....	1661	<i>Foltabs 500(PP)</i> .....	112, 1650
<i>Firazyr(ZI)</i> .....	113	<i>Fonat(AL)</i> .....	621
<i>Firmagon 120mg(FP)</i> .....	353	<i>FonatPlus (AF)</i> .....	625, 1664
<i>Firmagon 80mg(FP)</i> .....	353	<i>FonatPlus(AF)</i> .....	626
<i>Fixta 60 (DO)</i> .....	630	<b>FONDAPARINUX</b> .....	109
		<i>Foradile(SZ)</i> .....	736

<i>Formet 1000 (RW)</i> .....	64	<i>Gabapentin Aspen 800(RW)</i>	
<i>FORMET 500 (RF)</i> .....	65	.NERVOUS SYSTEM .....	663
<i>FORMET 850 (RF)</i> .....	65	<i>Gabapentin GH(GQ)</i>	
<i>Formet Aspen 500(RW)</i> .....	65	.Repatriation Pharmaceutical Benefits Scheme .....	1667
<i>Formet Aspen 850(RW)</i> .....	65	<i>Gabapentin GH(GQ)</i>	
<i>Forteo(LY)</i>		.NERVOUS SYSTEM .....	662
.MUSCULO-SKELETAL SYSTEM .....	631	<i>Gabapentin Sandoz (SZ)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		.NERVOUS SYSTEM .....	662
HORMONES AND INSULINS .....	233	<i>Gabitril(OA)</i> .....	660
<i>Forxiga(AP)</i> .....	88	GALANTAMINE.....	721
<i>Fosamax Plus 70 mg/140 mcg(MK)</i> .....	625, 1664	<i>Galantamine AN SR (EA)</i> .....	721, 722, 723
<i>Fosamax Plus D-Cal(MK)</i> .....	627, 1664	<i>Galantyl(AF)</i> .....	721, 722, 723
<i>Fosamax Plus(MK)</i> .....	626, 1664	<i>Galvumet 50/1000(NV)</i> .....	77
FOSAMPRENAVIR.....	1321	<i>Galvumet 50/500(NV)</i> .....	77
FOSAPREPITANT.....	48	<i>Galvumet 50/850(NV)</i> .....	77
<i>Fosetic 20/12.5 (ZP)</i> .....	138	<i>Galvus(NV)</i> .....	85
FOSINOPRIL.....	132	<i>Gamine XR (RW)</i> .....	721, 722, 723
FOSINOPRIL + HYDROCHLOROTHIAZIDE .....	137	GANCICLOVIR.....	912, 1150, 1319
<i>Fosinopril/HCT Actavis 20/12.5(EA)</i> .....	138	<i>Ganfort 0.3/5(AG)</i> .....	760
<i>Fosipril 10 (RW)</i> .....	132	<i>GANfort PF 0.3/5(AG)</i> .....	760, 761
<i>Fosipril 20 (RW)</i> .....	132	GANIRELIX .....	1629
<i>Fosrenol(ZI)</i> .....	784, 1077, 1316	<i>Gantin (EA)</i>	
<i>Fragmin(PF)</i> .....	93, 94, 95	.Repatriation Pharmaceutical Benefits Scheme .....	1667
<i>Frakas (RW)</i> .....	236	<i>Gantin(ED)</i> .....	1667
FRAMYCETIN SULFATE .....	783	GAPENTIN (RF)	
FRAMYCETIN SULFATE + GRAMICIDIN +		.NERVOUS SYSTEM .....	662, 663
DEXAMETHASONE.....	782	GAPENTIN(RF).....	662
<i>Fraxiparine Forte(AS)</i> .....	96	<i>Gastrex(CR)</i> .....	56, 1646
<i>Fraxiparine(AS)</i> .....	96, 97	GAUZE AND COTTON TISSUE COMBINE ROLL .....	1693
<i>FruitiVits(VF)</i> .....	826	GEFITINIB.....	304
<i>Frusax(ER)</i> .....	121	<i>Gelofusine(BR)</i> .....	112
FRUSEMIDE.....	24, 121	GEMFIBROZIL .....	167
<i>Fruzemide RBX (RA)</i> .....	121	<i>Generic Health Pty Ltd(GQ)</i> .....	650, 651, 1666
<i>Fruzemide RBX(RA)</i> .....	121	<i>Genoptic(AG)</i> .....	750
<i>Fruzemide Sandoz (SZ)</i> .....	24, 121	<i>Genotropin GoQuick(PF)</i> .....	1398, 1600, 1623
<i>Fruzemide Sandoz(SZ)</i> .....	121	<i>Genotropin MiniQuick(PF)</i> ... ..	1398, 1399, 1600, 1601, 1623, 1624
<i>Fruzemide-Clarix(AE)</i> .....	24, 121	<i>Genotropin(PF)</i> .....	1399, 1600, 1624
<i>Fucidin(CS)</i> .....	263	<i>Genox 10(AF)</i> .....	347
<i>Fungilin(QA)</i> .....	33	<i>Genox 20(AF)</i> .....	348
FUROSEMIDE AN (EA).....	121	<i>GenRx Aciclovir (GX)</i> .....	273
FUSIDATE.....	263	<i>GenRx Aciclovir(GX)</i> .....	273
<i>Fuzeon(RO)</i> .....	1335	<i>GenRx Amiodarone (GX)</i> .....	114
<i>Fybogel(RC)</i> .....	1645	<i>GenRx Baclofen(GX)</i> .....	619
<i>Fycempa(EI)</i> .....	667, 668	<i>GenRx Clomipramine(GX)</i> .....	702
<i>GA express 15(VF)</i> .....	811	<i>GenRx Cyproterone Acetate (GX)</i>	
<i>GA gel(VF)</i> .....	811	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>GA Tramadol SR 100mg(ED)</i> .....	648	AGENTS .....	349
<i>GA Tramadol SR 200mg(ED)</i> .....	648	.GENITO URINARY SYSTEM AND SEX HORMONES	
<i>GA1 Anamix infant(SB)</i> .....	811	.....	220
<i>GA1 Anamix Junior(NU)</i> .....	811	<i>GenRx Cyproterone Acetate(GX)</i>	
<i>Gabacor (CR)</i> .....	662	.ANTINEOPLASTIC AND IMMUNOMODULATING	
GABAPENTIN		AGENTS .....	349
.NERVOUS SYSTEM.....	661	.GENITO URINARY SYSTEM AND SEX HORMONES	
.Repatriation Pharmaceutical Benefits Scheme .....	1666	.....	220, 221
<i>Gabapentin 300(CR)</i> .....	1667	<i>GenRx Doxycycline (GX)</i> .....	233, 234, 235
<i>Gabapentin 400(CR)</i> .....	1667	<i>GenRx Doxycycline(GX)</i> .....	236
<i>Gabapentin AN (EA)</i> .....	662, 663	<i>GenRx Famotidine (GX)</i> .....	33, 34
<i>Gabapentin AN(EA)</i>		<i>GenRx Fluoxetine (GX)</i> .....	706
.Repatriation Pharmaceutical Benefits Scheme .....	1667	<i>GenRx Gabapentin (GX)</i> .....	662, 1667
<i>Gabapentin AN(EA)</i>		<i>GenRx Gabapentin(GX)</i>	
.NERVOUS SYSTEM.....	662	.Repatriation Pharmaceutical Benefits Scheme .....	1667
<i>Gabapentin Aspen 100 (RW)</i> .....	1666	<i>GenRx Gabapentin(GX)</i>	
<i>Gabapentin Aspen 100(RW)</i>		.NERVOUS SYSTEM .....	662, 663
.NERVOUS SYSTEM.....	662	<i>GenRx Gliclazide (GX)</i> .....	66
<i>Gabapentin Aspen 300 (RW)</i> .....	662, 1667	<i>GenRx Indapamide (GX)</i> .....	120
<i>Gabapentin Aspen 400 (RW)</i> .....	662, 1667	<i>GenRx Isosorbide Mononitrate(GX)</i> .....	117
<i>Gabapentin Aspen 600 (RW)</i> .....	1667	<i>GenRx Moclobemide(GX)</i> .....	708, 709
<i>Gabapentin Aspen 600(RW)</i>		<i>GenRx Norfloxacin(GX)</i> .....	262
.NERVOUS SYSTEM.....	662	<i>GenRx Paroxetine (GX)</i> .....	707
<i>Gabapentin Aspen 800 (RW)</i> .....	1667		

<i>GenRx Perindopril/ Indapamide 4/1.25 (GX)</i> .....	138	HALOPERIDOL DECANOATE.....	679
<i>GenRx Piroxicam(GX)</i> .....	613, 614	<i>Hamilton Skin Therapy Oil(KY)</i> .....	1653
<i>GenRx Tamoxifen (GX)</i> .....	348	<i>Hamilton Skin Therapy Wash(KY)</i> .....	1657
<i>GenRx Terbinafine (GX)</i> .....	192	<i>Handy 36361414(BV)</i> .....	1674
<i>GenRx Terbinafine(GX)</i> .....	1652	<i>Handy 71117-05(BV)</i> .....	1685
GENTAMICIN		<i>Handy 71117-06(BV)</i> .....	1685
.ANTIINFECTIVES FOR SYSTEMIC USE .....	258	<i>Handygauze Cohesive 8631(BV)</i> .....	1675
.SENSORY ORGANS .....	750	<i>Handygauze Cohesive 8633(BV)</i> .....	1675
<i>Genteal gel(NV)</i> .....	777, 778	<i>Handygauze Cohesive 8635(BV)</i> .....	1675
<i>Genteal(NV)</i> .....	776, 777	<i>Harvoni(GI)</i> .....	280, 915, 916, 1153
<i>Genvoya(GI)</i> .....	1335	<i>HCU Anamix infant(SB)</i> .....	812
<i>Gilenya(NV)</i> .....	365	<i>HCU Anamix junior LQ(SB)</i> .....	810
GLATIRAMER ACETATE .....	357	<i>HCU Anamix Junior(NU)</i> .....	812
<i>Gliadel(EI)</i> .....	284	<i>HCU cooler 10(VF)</i> .....	812
GLIBENCLAMIDE.....	66	<i>HCU cooler 15(VF)</i> .....	812
GLICLAZIDE.....	66	<i>HCU cooler 20(VF)</i> .....	812
GLIMEPIRIDE.....	66	<i>HCU express 15(VF)</i> .....	812
<i>Glimepiride AN(EA)</i> .....	66, 67	<i>HCU gel(VF)</i> .....	812
<i>Glimepiride Sandoz (SZ)</i> .....	66, 67	<i>HCU Lophlex LQ 20(SB)</i> .....	812
GLIPIZIDE .....	67	HEPARIN SODIUM .....	96
<i>Glivanib (JU)</i> .....	307, 308, 309, 310, 312, 314, 316, 317	<i>Hepsera (GI)</i> .....	1323
<i>Glivec(AF)</i> .....	306, 307, 308, 309, 310, 311, 312, 314, 316, 317	<i>Hequinel(RW)</i> .....	618
<i>GlucaGen Hypokit(NO)</i> .....	24, 232	<i>Herceptin SC(RO)</i> .....	290, 291, 292
GLUCAGON HYDROCHLORIDE.....	24, 232	<i>Herron ClearLax(ON)</i> .....	53, 830
<i>Glucobay 100 (BN)</i> .....	78	HEXAMINE HIPPURATE .....	265
<i>Glucobay 50 (BN)</i> .....	78	HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE .....	822, 823
<i>Glucobete 1000(DO)</i> .....	64	<i>Hiprex(IA)</i> .....	265
<i>Glucobete 500 (DO)</i> .....	65	HONEY BEE VENOM .....	783
<i>Glucobete 850 (DO)</i> .....	65	<i>Hospira Cefazolin Sodium (PF)</i> .....	248
GLUCOSE AND KETONE INDICATOR URINE .....	787	<i>Hospira Ceftriaxone(PF)</i> .....	252
GLUCOSE INDICATOR URINE .....	787	<i>Hospira Pty Limited (PF)</i> .....	24, 227
<i>Glucovance 250mg/1.25mg(AL)</i> .....	73	<i>Hospira Pty Limited(PF)</i>	
<i>Glucovance 500mg/2.5mg(AL)</i> .....	73	.Highly Specialised Drugs Program (Private Hospital)909, 1077	
<i>Glucovance 500mg/5mg(AL)</i> .....	73	.Highly Specialised Drugs Program (Public Hospital)1147, 1316	
<i>Glyade MR(AF)</i> .....	66	.Prescriber Bag .....	24, 25, 26
<i>Glyade(AF)</i> .....	66	<i>Hospira Pty Limited(PF)</i>	
GLYBOSAY(RW).....	78	.ALIMENTARY TRACT AND METABOLISM .....	50
GLYCEROL .....	1645	<i>Hospira Pty Limited(PF)</i>	
GLYCERYL TRINITRATE.....	24, 116, 117	.BLOOD AND BLOOD FORMING ORGANS .....	96
GLYCINE WITH CARBOHYDRATE .....	820	<i>Hospira Pty Limited(PF)</i>	
<i>Glycine500(VF)</i> .....	821	.BLOOD AND BLOOD FORMING ORGANS .....	96
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS .....	821	<i>Hospira Pty Limited(PF)</i>	
GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACID AND DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE .....	822	.ANTIINFECTIVES FOR SYSTEMIC USE .....	242
GLYCOPYRRONIUM .....	744	<i>Hospira Pty Limited(PF)</i>	
<i>Glycosade(VF)</i> .....	803	.ANTIINFECTIVES FOR SYSTEMIC USE .....	242
Gold Cross(BI)		<i>Hospira Pty Limited(PF)</i>	
.Repatriation Pharmaceutical Benefits Scheme .....	1662, 1663, 1671	.ANTIINFECTIVES FOR SYSTEMIC USE .....	247
GOLIMUMAB.....	525, 528, 532, 534, 537, 540	<i>Hospira Pty Limited(PF)</i>	
<i>Gonal-f Pen(SG)</i> .....	218, 1627	.ANTIINFECTIVES FOR SYSTEMIC USE .....	247
<i>Gopten(GO)</i> .....	137	<i>Hospira Pty Limited(PF)</i>	
GOSERELIN.....	344	.ANTIINFECTIVES FOR SYSTEMIC USE .....	250
GOSERELIN (&) BICALUTAMIDE.....	344	<i>Hospira Pty Limited(PF)</i>	
GRANISETRON .....	43	.ANTIINFECTIVES FOR SYSTEMIC USE .....	250
<i>Granisetron Kabi (PK)</i> .....	43	<i>Hospira Pty Limited(PF)</i>	
<i>Granisetron-AFT(AE)</i> .....	43	.ANTIINFECTIVES FOR SYSTEMIC USE .....	251
<i>Granocyte 13(PF)</i> .....	926, 1164	<i>Hospira Pty Limited(PF)</i>	
<i>Granocyte 34(PF)</i> .....	926, 1164	.ANTIINFECTIVES FOR SYSTEMIC USE .....	258
GRAZOPREVIR + ELBASVIR .....	279, 914, 915, 1152	<i>Hospira Pty Limited(PF)</i>	
GRISEOFULVIN .....	191	.ANTIINFECTIVES FOR SYSTEMIC USE .....	262
<i>Grisovin 500(QA)</i> .....	191	<i>Hospira Pty Limited(PF)</i>	
<i>Grisovin(QA)</i> .....	191	.ANTIINFECTIVES FOR SYSTEMIC USE .....	262
<i>Gynotril (ER)</i> .....	352	<i>Hospira Pty Limited(PF)</i>	
<i>Haldol decanoate(JC)</i> .....	679	.ANTIINFECTIVES FOR SYSTEMIC USE .....	262
HALOPERIDOL .....	23, 678	<i>Hospira Pty Limited(PF)</i>	

.ANTIINFECTIVES FOR SYSTEMIC USE.....	262	<i>Hydroxychloroquine GH(GQ)</i> .....	618
<i>Hospira Pty Limited(PF)</i>		<i>Hydroxychloroquine RBX (RA)</i> .....	618
.ANTIINFECTIVES FOR SYSTEMIC USE.....	263	HYDROXYUREA.....	337
<i>Hospira Pty Limited(PF)</i>		<i>Hygroton 25(GH)</i> .....	120
.ANTIINFECTIVES FOR SYSTEMIC USE.....	263	<i>Hylo-Forte(AE)</i> .....	781
<i>Hospira Pty Limited(PF)</i>		<i>Hylo-Fresh(AE)</i> .....	781
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Hymenoptera Honey Bee Venom(DE)</i> .....	783
AGENTS.....	286	HYOSCINE BUTYLBROMIDE .....	24, 829, 1644
<i>Hospira Pty Limited(PF)</i>		<i>HYOSCINE BUTYLBROMIDE SXP (XC)</i> .....	24, 829
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Hypnodorm(AF)</i> .....	1669
AGENTS.....	287	HYPROMELLOSE.....	776, 777
<i>Hospira Pty Limited(PF)</i>		HYPROMELLOSE + CARBOMER-980.....	777
.NERVOUS SYSTEM.....	633	<i>Hypurin Isophane(AS)</i> .....	63
<i>Hospira Pty Limited(PF)</i>		<i>Hypurin Neutral(AS)</i> .....	63
.NERVOUS SYSTEM.....	633	<i>Hysone 20(AF)</i> .....	228
<i>Hospira Pty Limited(PF)</i>		<i>Hysone 4(AF)</i> .....	228
.NERVOUS SYSTEM.....	633	<i>lalex (LN)</i> .....	246, 247
<i>Hospira Pty Limited(PF)</i>		<i>lalex(LN)</i> .....	245, 246, 247
.NERVOUS SYSTEM.....	634	IBANDRONATE .....	622, 1051, 1290
<i>Hospira Pty Limited(PF)</i>		<i>Ibavyr(IX)</i> .....	276, 277, 913, 1150, 1151
.NERVOUS SYSTEM.....	634	<i>Ibilex 125(AF)</i> .....	246, 247
<i>Hospira Pty Limited(PF)</i>		<i>Ibilex 250 (AF)</i> .....	245, 246, 247
.NERVOUS SYSTEM.....	634	<i>Ibilex 250(AF)</i> .....	246
<i>Hospira Pty Limited(PF)</i>		<i>Ibilex 500(AF)</i> .....	246, 247
.NERVOUS SYSTEM.....	635	IBRUTINIB.....	305
<i>Hospira Pty Limited(PF)</i>		IBUPROFEN .....	614, 832
.NERVOUS SYSTEM.....	697	ICATIBANT.....	112
<i>Hospira Pty Limited(PF)</i>		ICHTHAMMOL .....	1656
.NERVOUS SYSTEM.....	698	ICHTHAMMOL + ZINC OXIDE.....	1656
<i>Hospira Pty Limited(PF)</i>		<i>Iclusig(TS)</i> .....	329, 330
.RESPIRATORY SYSTEM.....	749	<i>Idaprex 2 (SZ)</i> .....	134
<i>HPMC PAA(NM)</i> .....	777, 778	<i>Idaprex 4 (SZ)</i> .....	134
<i>Humalog KwikPen (KP)</i> .....	62	<i>Idaprex 8 (SZ)</i> .....	134
<i>Humalog Mix25 KwikPen (KP)</i> .....	64	<i>Idaprex Combi 4/1.25(SZ)</i> .....	138
<i>Humalog Mix25(LY)</i> .....	64	IDARUBICIN.....	288
<i>Humalog Mix50 KwikPen (KP)</i> .....	64	IDELALISIB .....	338
<i>Humalog Mix50(LY)</i> .....	64	<i>Ikorel(SW)</i> .....	117, 118
<i>Humalog(LY)</i> .....	62	<i>Ikotab (QA)</i> .....	117, 118
HUMAN CHORIONIC GONADOTROPHIN .....	219, 1628	ILOPROST .....	873, 1110
HUMAN MENOPAUSAL GONADOTROPHIN.....	1628	IMATINIB.....	305, 306, 308, 309, 310, 311, 312, 314, 316
<i>Humatrope(LY)</i> .....	1389, 1502, 1540	<i>IMATINIB AN(EA)</i> ... 307, 308, 309, 310, 312, 314, 316, 317	
<i>Humira(VE)</i> .... 377, 379, 382, 385, 386, 387, 390, 393, 394,		<i>Imatinib GH (GQ)</i> .... 307, 308, 309, 310, 312, 314, 316, 317	
397, 401, 403, 406, 408, 409, 413, 417, 421, 424, 428,		<i>IMATINIB RBX (RA)</i> 307, 308, 309, 310, 312, 314, 316, 317	
429, 432, 436, 441, 964, 1202, 1203		<i>Imatinib-APOTEX (TX)</i> .. 307, 308, 309, 310, 312, 314, 316,	
<i>Humulin 30/70(LY)</i> .....	63, 64	317	
<i>Humulin NPH(LY)</i> .....	63	<i>IMATINIB-DRLA(RZ)</i> .... 307, 308, 309, 310, 312, 314, 316,	
<i>Humulin R (LY)</i> .....	63	317	
<i>Hycor(QA)</i> .....	754	<i>Imatinib-Teva(TB)</i> .....	307, 308, 309, 310, 314, 316, 317
<i>Hydopa(AF)</i> .....	118	<i>Imazan (ER)</i> .....	608
HYDRALAZINE.....	119	<i>Imbruvica(JC)</i> .....	305
<i>Hydrea(BQ)</i> .....	337	<i>Imdur 120 mg(AP)</i> .....	117
<i>Hydrene 25/50(AF)</i> .....	122	<i>Imdur Durule(AP)</i> .....	117
HYDROCHLOROTHIAZIDE .....	120	<i>Imigran FDT(AS)</i> .....	655
HYDROCHLOROTHIAZIDE + TRIAMTERENE .....	122	<i>Imigran(AS)</i> .....	655
<i>Hydrocoll 900744(HR)</i> .....	1689	<i>Imigran(LN)</i> .....	655
<i>Hydrocoll 900936(HR)</i> .....	1689	IMIPRAMINE.....	702
<i>Hydrocoll Thin 900758(HR)</i> .....	1688	IMIQUIMOD.....	207, 1656, 1657
HYDROCORTISONE .....	227	<i>Imodium(JT)</i> .....	56
HYDROCORTISONE ACETATE		<i>Imovane(SW)</i> .....	1669
.ALIMENTARY TRACT AND METABOLISM .....	57	<i>Implanon NXT(MK)</i> .....	210
.DERMATOLOGICALS .....	194	<i>Imrest(AF)</i> .....	1669
.Repatriation Pharmaceutical Benefits Scheme .....	1654	<i>Imukin(BY)</i> .....	930, 1168
.SENSORY ORGANS .....	754	<i>Imuran (AS)</i> .....	608
HYDROCORTISONE SODIUM SUCCINATE.....	24, 228	<i>Imuran(AS)</i> .....	608
HYDROMORPHONE.....	631, 632	<i>In a Wink Moisturising(NM)</i> .....	776, 777
<i>Hydrosorb 900854(HR)</i> .....	1692	<i>Inadine(KI)</i> .....	1694
<i>Hydroxo-B12(AS)</i> .....	112	INCUBOTULINUMTOXINA .....	1346, 1347
HYDROXOCOBALAMIN.....	111, 1649	<i>Incruse Ellipta(GK)</i> .....	746
HYDROXYCHLOROQUINE .....	617	INDACATEROL .....	736
<i>Hydroxychloroquine AN (EA)</i> .....	618	INDACATEROL + GLYCOPYRRONIUM .....	742

INDAPAMIDE .....	120	IRBESARTAN .....	142
INDAPAMIDE AN SR(EA) .....	120	IRBESARTAN + HYDROCHLOROTHIAZIDE .....	146
Indapamide AN(EA) .....	120	Irbesartan Actavis 150(ED) .....	142
Indapamide Sandoz (SZ) .....	120	Irbesartan Actavis 300(ED) .....	143
Inderal(AP) .....	123, 124	Irbesartan Actavis 75(ED) .....	143
INDINAVIR .....	1321	Irbesartan AMNEAL (EF) .....	142, 143
Indocid(AS) .....	611, 612, 832	Irbesartan AN(EA) .....	142, 143
INDOMETHACIN .....	611, 832	Irbesartan GH (GQ) .....	142, 143
Indosyl Combi 4/1.25 (RW) .....	138	Irbesartan HCT Actavis 150/12.5(ED) .....	147
Indosyl Mono 2(RW) .....	134	Irbesartan HCT Actavis 300/12.5(ED) .....	146
Indosyl Mono 4(RW) .....	134	Irbesartan HCT Actavis 300/25(ED) .....	147
Indosyl Mono 8(RW) .....	135	Irbesartan HCT GH 150/12.5 (GQ) .....	147
Infectra(PF)971, 975, 979, 984, 989, 994, 998, 1003, 1010, 1210, 1213, 1218, 1223, 1227, 1231, 1237, 1241, 1248		Irbesartan HCT GH 300/12.5 (GQ) .....	146
INFLIXIMAB.970, 971, 975, 979, 984, 989, 994, 998, 1003, 1209, 1210, 1213, 1218, 1223, 1228, 1231, 1237, 1241, 1662		Irbesartan HCT GH 300/25 (GQ) .....	147
INGENOL MEBUTATE .....	1654	Irbesartan HCTZ AMNEAL (EF) .....	146, 147
Inlyta(PF) .....	293	Irbesartan HCTZ AN 150/12.5(EA) .....	147
iNova Pharmaceuticals (Australia) Pty Ltd(IA) .....	732	Irbesartan HCTZ AN 300/12.5(EA) .....	147
Inpler(AF) .....	122	Irbesartan HCTZ AN 300/25(EA) .....	147
Insig(RW) .....	120	Irbesartan RBX(RA) .....	142, 143
Inspra (PF) .....	122	Irbesartan Sandoz (SZ) .....	142, 143
INSULIN ASPART .....	62	Irbesartan Sandoz(SZ) .....	143
INSULIN ASPART + INSULIN ASPART PROTAMINE ...	63	Irbesartan/HCT Sandoz(SZ) .....	146, 147
INSULIN DETEMIR .....	64	Irbesartan/HCTZ RBX 150/12.5 (RA) .....	147
INSULIN GLARGINE .....	64	Irbesartan/HCTZ RBX 300/25 (RA) .....	147
INSULIN GLULISINE .....	62	Ircal(PE) .....	778, 779
INSULIN ISOPHANE BOVINE .....	63	Iressa(AP) .....	305
INSULIN ISOPHANE HUMAN .....	63	IRON .....	110
INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN .....	63	IRON POLYMALTOSE .....	110, 111
INSULIN LISPRO .....	62	IRON SUCROSE .....	111
INSULIN LISPRO + INSULIN LISPRO PROTAMINE ...	64	Irprestan 150(ZP) .....	142
INSULIN NEUTRAL BOVINE .....	62	Irprestan 300(ZP) .....	143
INSULIN NEUTRAL HUMAN .....	63	Irprestan 75 (ZP) .....	143
Intal CFC-Free(SW) .....	746	Iscover (AV) .....	98, 99
Intal Forte CFC-Free(SW) .....	746	Iscover(AV) .....	1649
Intal Spincaps(EA) .....	746	Isentress(MK) .....	1336, 1337
Integrilin(MK) .....	101	Isoleucine 1000(VF) .....	823
Intelence(JC) .....	1329	Isoleucine 50(VF) .....	823
INTERFERON ALFA-2A .....	353, 354, 929, 1167, 1337	ISOLEUCINE WITH CARBOHYDRATE .....	823
INTERFERON ALFA-2B .....	354, 929, 1168, 1337	Isomonit (SZ) .....	117
INTERFERON BETA-1A .....	355	ISONIAZID .....	271
INTERFERON BETA-1B .....	355	Isoptin 180 SR(GO) .....	130
INTERFERON GAMMA-1B .....	930, 1168	Isoptin SR(GO) .....	130
Intrasite Gel 7313(SN) .....	1691	Isoptin(GO) .....	131
Intron A Redipen(MK) .....	354, 929, 930, 1168, 1338	Isopto Carpine(NV) .....	756
Intron A(MK) .....	929, 1168, 1338	Isordil Sublingual(RW) .....	117
Invega Sustenna(JC) .....	690, 691	Isosorbide AN(EA) .....	117
Invega Trinza(JC) .....	691	ISOSORBIDE DINITRATE .....	117
Invega(JC) .....	690	ISOSORBIDE MONONITRATE .....	117
Invirase(RO) .....	1322	ISOTRETINOIN .....	205
Inza 250(AF) .....	615, 616, 833	Isotretinoin AN(EA) .....	206
Inza 500(AF) .....	615, 616, 833	Isotretinoin SCP 20 (CR) .....	206
Iodosorb 66051330(SN) .....	1678	Itracap (AF) .....	268
Iodosorb 66051340(SN) .....	1678	ITRACONAZOLE .....	267
Iodosorb 66051360(SN) .....	1678	ITRANOX(RW) .....	268
Iodosorb Ointment 66051230(SN) .....	1679	IVABRADINE .....	118
Iodosorb Ointment 66051240(SN) .....	1678	IVACAFTOR .....	1071, 1073, 1311, 1312
Iodosorb Powder 66051070(SN) .....	1679	IVERMECTIN .....	735
Ionil-T(GA) .....	1655	IXEKIZUMAB .....	544, 549
lopidine 0.5%(NV) .....	755	Jakavi(NV) .....	331, 332
l-Pantoprazole(CR) .....	39, 40	Janumet XR(MK) .....	76
lpratin Adult(AF) .....	745	Janumet(MK) .....	76
lpratin(AF) .....	745	Januvia(MK) .....	84
IPRATROPIUM .....		Jardiamet 12.5 mg/1000 mg(BY) .....	70, 71
.Repatriation Pharmaceutical Benefits Scheme .....	1670	Jardiamet 12.5 mg/500 mg(BY) .....	70, 71
.RESPIRATORY SYSTEM .....	745	Jardiamet 5 mg/1000 mg(BY) .....	70, 71
lptam(AL) .....	655	Jardiamet 5 mg/500 mg(BY) .....	70, 71
		Jardiance(BY) .....	89
		Jelonet 7404(SN) .....	1685
		Jetrea(NV) .....	778
		JJ 12010(JJ) .....	1693

Jurnista(JC)	633	Lamivudine 150 mg + Zidovudine 300 mg Alphapharm (AF)	1333
Kaletra(VE)	1333	Lamivudine Alphapharm (AF)	1325
Kalixocin (AF)	254	LAMOTRIGINE	665
Kalma 0.25 (AF)	697	Lamotrigine AN (EA)	665, 666
Kalma 0.25(AF)	697	Lamotrigine Aspen 100(RW)	666
Kalma 0.5 (AF)	696	Lamotrigine Aspen 200(RW)	665
Kalma 1 (AF)	696	Lamotrigine Aspen 25(RW)	665
Kaltostat 168117(CC)	1679	Lamotrigine Aspen 5 (RW)	666
Kaltostat 168210(CC)	1680	Lamotrigine Aspen 50(RW)	665
Kaltostat 168212(CC)	1679	Lamotrigine generichealth (HQ)	665, 666
Kalydeco(VR)	1073, 1076, 1312, 1315	Lamotrigine GH (GQ)	665
Kapanol(YN)	636, 637	Lamotrigine GH(GQ)	665, 666
Kaptan (ER)	686, 687, 688	Lamotrigine Sandoz (SZ)	665, 666
Karlor CD(LN)	249	Lamotrigine Sandoz(SZ)	665
Karvea (SW)	143	Lanoxin(QA)	113
Karvezide 150/12.5 (SW)	147	Lanoxin-PG(QA)	113
Karvezide 300/12.5 (SW)	147	Lanpro(JU)	761
Karvezide 300/25 (SW)	147	LANREOTIDE	907, 1144, 1145
Keflex(AS)	246, 247	LANSOPRAZOLE	37
Keflor CD (AF)	249	Lansoprazole ODT GH (GQ)	37
Keflor(AF)	249	LANTHANUM	784, 1077, 1316
Kenacomb Otic(QA)	782	Lantim (JU)	761, 762
Kenacort-A10(QA)	230	Lantus SoloStar (AV)	64
Keppra (UC)	666, 667	Lantus(SW)	64
Kerron 1000(DO)	666	Lanvis(AS)	287
Kerron 250(DO)	666	Lanzopran (RA)	37, 38
Kerron 500(DO)	666	LAPATINIB	317
Kerron(DO)	667	Largactil(SW)	23, 677
KetoCal 3		Lasix(SW)	24, 121
1(SB)	823	Lasix-M(SW)	121
KetoCal 4		LATANOPROST	761
1 LQ(SB)	822	LATANOPROST + TIMOLOL	761
1(SB)	823	Latanoprost Actavis (EA)	761
KETOCONAZOLE	190, 1651	Latanoprost GH(GQ)	761
Keto-Diastix(BN)	787	Latanoprost Sandoz (SZ)	761
KETOPROFEN	614	Latanoprost/timolol AN 50/5(EA)	761, 762
Kevtam (AF)	666	Latanoprost/Timolol Sandoz 50/5 (SZ)	761, 762
Kevtam 1000 (AF)	666	Latuda(SE)	679
Keyo(VF)	822	LaxaCon(EA)	53, 830
keyomega(VF)	818	lax-sachets (AE)	53, 830
Kindergen(SB)	827	Lax-Tab(AE)	51, 830
Kineret(FK)	1010, 1249	Ledip (RA)	129
Kinson(AF)	672	LEDIPASVIR + SOFOSBUVIR	279, 280, 915, 1152, 1153
Kivexa(VI)	1330	LEFLUNOMIDE	365, 366
Klacid(GO)	255	Leflunomide AN (EA)	366
Kombiglyze XR 2.5/1000(AP)	75	Leflunomide APOTEX (GX)	366
Kombiglyze XR 5/1000(AP)	75	Leflunomide APOTEX(GX)	366
Kombiglyze XR 5/500(AP)	75	Leflunomide GH (GQ)	366
Konakion MM(RO)	26	Leflunomide Sandoz(SZ)	366
Kosteo (RW)		Lemtrada(GZ)	937, 1175, 1176
ALIMENTARY TRACT AND METABOLISM	90	LENALIDOMIDE	1039, 1041, 1042, 1278, 1279, 1281
MUSCULO-SKELETAL SYSTEM	628	Lenest 30 ED (AF)	210
KSART HCT 150/12.5(RW)	147	Lengout(LN)	620
KSART HCT 300/12.5 (RW)	147	LENOGRASTIM	924, 1162
KSART HCT 300/25(RW)	147	LENVATINIB	318
Kuvan(IO)	93	Lenvima(EI)	319
Kytril(IX)	43	Lercadip(EA)	129
LABETALOL	128	Lercan (RW)	129
LACOSAMIDE	663, 664	LERCANIDIPINE	129
Lamictal(AS)	665, 666	LERCANIDIPINE + ENALAPRIL	139
Lamidus (RA)	665, 666	Lercanidipine GH(GQ)	129
Lamisil (Novartis Pharmaceuticals Australia Pty Limited)		Lercanidipine Sandoz (SZ)	129
(NV)	1652	Lescol XL(NV)	156
Lamisil (Novartis Pharmaceuticals Australia Pty Limited)(NV)	192	Letroz(JU)	352
Lamisil DermGel(GK)	1651	LETROZOLE	352
Lamisil(GK)	191, 1651	Letrozole AN (EA)	352
LAMITAN(RF)	665, 666	Letrozole FBM(FO)	352
LAMIVUDINE	1325, 1326	Letrozole generichealth (GQ)	352
LAMIVUDINE + ZIDOVUDINE	1332	Letrozole RBX(RA)	353

<i>Letrozole Sandoz (SZ)</i> .....	353	.CARDIOVASCULAR SYSTEM.....	115
<i>Leucovorin Calcium (Hospira Pty Limited) (PF)</i> .....	785	<i>Link Medical Products Pty Ltd(LM)</i>	
<i>Leucovorin Calcium (Hospira Pty Limited)(PF)</i> .....	785, 786	.DERMATOLOGICALS.....	207
<i>Leucovorin Calcium (Pfizer Australia Pty Ltd)(PF)</i> .....	785, 786	<i>Link Medical Products Pty Ltd(LM)</i>	
<i>Leukeran(AS)</i> .....	283	.DERMATOLOGICALS.....	207
<i>Leukoflex 1124(BV)</i> .....	1695	<i>Link Medical Products Pty Ltd(LM)</i>	
<i>Leukoplast 01071-00(BV)</i> .....	1694	.ANTIINFECTIVES FOR SYSTEMIC USE.....	272
<i>Leukoplast 01072-00(BV)</i> .....	1694	<i>Link Medical Products Pty Ltd(LM)</i>	
<i>Leukoplast 01073-00(BV)</i> .....	1694	.ANTIINFECTIVES FOR SYSTEMIC USE.....	272
<i>Leukopor 2471(BV)</i> .....	1694	<i>Link Medical Products Pty Ltd(LM)</i>	
<i>Leukopor 2472(BV)</i> .....	1695	.RESPIRATORY SYSTEM.....	746
<i>Leukopor 2474(BV)</i> .....	1695	<i>Link Medical Products Pty Ltd(LM)</i>	
<i>Leukosilk 1021(BV)</i> .....	1694	.RESPIRATORY SYSTEM.....	746
<i>Leukosilk 1022(BV)</i> .....	1695	<i>Lioresal 10 (NV)</i> .....	619
<i>Leukosilk 1024(BV)</i> .....	1695	<i>Lioresal 25 (NV)</i> .....	619
LEUPRORELIN.....	345, 346	<i>Lioresal Intrathecal (NV)</i> .....	1051, 1289
LEUPRORELIN (&) INERT SUBSTANCE (&)		LIOTHYRONINE.....	230
BICALUTAMIDE		LIPEGFILGRASTIM.....	926, 1164
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Lipex 10(FR)</i> .....	164, 165
AGENTS.....	346, 350	<i>Lipex 20(FR)</i> .....	164, 166
<i>Levactam(ER)</i> .....	666	<i>Lipex 40(FR)</i> .....	165, 166
<i>Levecetam 1000 (RZ)</i> .....	666	<i>Lipex 80(FR)</i> .....	164, 165
<i>Levecetam 250 (RZ)</i> .....	666	<i>Lipidil(GO)</i> .....	166, 167
<i>Levecetam 500 (RZ)</i> .....	666	<i>Lipigem (AF)</i> .....	167
<i>Levemir FlexPen(NF)</i> .....	64	<i>Lipistart(VF)</i> .....	803
<i>Levemir Penfill (NO)</i> .....	64	<i>Lipitor(PF)</i> .....	153, 154, 155
LEVETIRACETAM.....	666, 667	<i>Liposomal Doxorubicin SUN (RA)</i> .....	920, 1157
<i>Levetiracetam AN(EA)</i> .....	666	<i>Lipostat 10 (RF)</i> .....	156, 157
<i>Levetiracetam GH (GQ)</i> .....	666	<i>Lipostat 20 (RF)</i> .....	156, 157
<i>Levetiracetam SZ(SZ)</i> .....	666, 667	<i>Lipostat 40 (RF)</i> .....	156, 158
<i>Levetiracetam-AFT (AE)</i> .....	667	<i>Lipostat 80 (RF)</i> .....	157, 158
<i>Levi 1000 (RW)</i> .....	666	<i>Liquifilm Tears(AG)</i> .....	780, 781
<i>Levi 250 (RW)</i> .....	666	<i>Liquigen(SB)</i> .....	788
<i>Levi 500 (RW)</i> .....	667	LISDEXAMFETAMINE.....	716
<i>Levitaccord(RA)</i> .....	666	LISINOPRIL.....	133
<i>Levitra(BN)</i> .....	1659	<i>Lisinopril AN(EA)</i> .....	133
<i>Levlen ED(SY)</i> .....	210	<i>Lisinopril generichealth (GQ)</i> .....	133
LEVOCABASTINE		<i>Lisinopril Sandoz(SZ)</i> .....	133
.Repatriation Pharmaceutical Benefits Scheme.....	1670, 1672	<i>Lithicarb(AS)</i> .....	710
LEVODOPA + BENSERAZIDE.....	671	LITHIUM CARBONATE.....	710
LEVODOPA + CARBIDOPA ANHYDROUS.....	671, 672, 1052, 1291	<i>Livostin(JT)</i>	
LEVODOPA + CARBIDOPA ANHYDROUS +		.Repatriation Pharmaceutical Benefits Scheme.....	1670, 1672
ENTACAPONE.....	672	<i>Locasol(SB)</i> .....	810
LEVONORGESTREL		<i>Loceryl(GA)</i> .....	1651
.GENITO URINARY SYSTEM AND SEX HORMONES		<i>Lodam SR 100 (ZP)</i> .....	648
.....	207, 210	<i>Lodam SR 150(ZP)</i> .....	647
LEVONORGESTREL + ETHINYLOESTRADIOL		<i>Lofenoxal(IA)</i> .....	56
.GENITO URINARY SYSTEM AND SEX HORMONES		<i>Logem (AL)</i> .....	665
.....	209, 210	<i>Logem(AL)</i> .....	665, 666
<i>Lexam 10 (RW)</i> .....	704	<i>Logicin Rapid Relief(QA)</i> .....	1670
<i>Lexam 20 (RW)</i> .....	704	<i>Logicin Sinus(QA)</i> .....	1671
<i>Lexapro(LU)</i> .....	704, 705, 706	<i>Logynon ED(SY)</i> .....	210
<i>Lexotan(RO)</i> .....	1668	<i>Lomotil(IV)</i> .....	56
LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE		<i>Loniten(PF)</i> .....	120
DISODIUM.....	1657	<i>Lonquex(TB)</i> .....	927, 1165
LIGNOCAINE		LOPERAMIDE.....	56, 1646
.CARDIOVASCULAR SYSTEM.....	113	LOPINAVIR + RITONAVIR.....	1333
.Prescriber Bag.....	25	<i>Lopresor 100(NV)</i> .....	126
.Repatriation Pharmaceutical Benefits Scheme.....	1653	<i>Lopresor 50(NV)</i> .....	126
LINAGLIPTIN.....	80	<i>Lorano(SZ)</i> .....	1672
LINAGLIPTIN + METFORMIN.....	71	LORATADINE.....	1672
<i>Lincocin(PF)</i> .....	258	<i>Lorstat 10 (AF)</i> .....	154, 155
LINCOMYCIN.....	258	<i>Lorstat 20 (AF)</i> .....	154, 155
<i>Link Medical Products Pty Ltd(LM)</i>		<i>Lorstat 40 (AF)</i> .....	153, 155
.Prescriber Bag.....	23	<i>Lorstat 80 (AF)</i> .....	154, 155
<i>Link Medical Products Pty Ltd(LM)</i>		LOSARTAN.....	143
.CARDIOVASCULAR SYSTEM.....	115	<i>Losac Tablets(AP)</i> .....	38, 39
<i>Link Medical Products Pty Ltd(LM)</i>		<i>Lovan 20 Tab(AL)</i> .....	706
		<i>Lovan(AL)</i> .....	706

<i>Lovir</i> (EA).....	273	<i>Mayne Pharma Erythromycin</i> (YT).....	255
<i>LoxaLate</i> (AF).....	704	<i>Mayne Pharma Oxycodone IR</i> (YN).....	638, 639
<i>Loxip 500</i> (DO).....	260	<i>MCT Oil</i> (SB).....	788
<i>Loxip 750</i> (DO).....	261	<i>MCT Pro-Cal</i> (VF).....	825
<i>Lozanoc</i> (YN).....	268	MEBENDAZOLE.....	1670
<i>LPV</i> (IA).....	239, 240	MEBEVERINE.....	1643
LUBRICATING AGENT.....	1674	<i>Medipore 2961</i> (MM).....	1694
<i>Lubri-Gel</i> (PP).....	1674	MEDIUM CHAIN TRIGLYCERIDES.....	787, 788
<i>Lucentis</i> (NV).....	767, 769, 771	MEDROXYPROGESTERONE	
<i>Lucrin Depot 3 Month PDS</i> (VE).....	345	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Lucrin Depot 4 Month PDS</i> (VE).....	345	AGENTS.....	343
<i>Lucrin Depot 6-Month</i> (VE).....	345	.GENITO URINARY SYSTEM AND SEX HORMONES	
<i>Lucrin Depot 7.5mg PDS</i> (VE).....	346	.....	211, 216
<i>Lucrin Depot Paediatric 30 mg PDS</i> (VE).....	345, 346	MEFENAMIC ACID.....	617
<i>Lukair</i> (AL).....	748, 749	<i>Mefix 310250</i> (MH).....	1694
<i>Lumigan PF</i> (AG).....	760	<i>Megafol 0.5</i> (AF).....	112, 1650
<i>Lumigan</i> (AG).....	760	<i>Megafol 5</i> (AF).....	112, 1650
<i>Lumin 10</i> (AF).....	711	<i>Mekinist</i> (NV).....	336, 337
<i>Lumin 20</i> (AF).....	710	<i>Melizide</i> (AF).....	67
<i>Lunava 10</i> (ZP).....	366	<i>Melolin 36361357</i> (SN).....	1693
<i>Lunava 20</i> (ZP).....	366	<i>Melolin 66974933</i> (SN).....	1692
LURASIDONE.....	679	<i>Meloxiauro 15</i> (DO).....	612
LUTROPIN ALFA.....	1629	<i>Meloxiauro 7.5</i> (DO).....	612
<i>Luveris</i> (SG).....	1629	<i>Meloxibell</i> (GQ).....	612
<i>Luvox</i> (GO).....	706	MELOXICAM.....	612
<i>Lycinate</i> (RF).....	116	<i>Meloxicam AN</i> (EA).....	612, 613
<i>Lyclear</i> (JT).....	735	<i>Meloxicam Ranbaxy</i> (RA).....	612, 613
<i>Lynparza</i> (AP).....	340, 341	<i>Meloxicam Sandoz</i> (SZ).....	612, 613
LYPRALIN(RW).....	652	<i>Meloxicam Sandoz</i> (SZ).....	612, 613
<i>Lyrca</i> (PF).....	652	<i>Meloxicam-GA</i> (ED).....	612, 613
<i>Lyzalon</i> (AF).....	652, 653	MELPHALAN.....	283
<i>Mabthera SC</i> (RO).....	288, 289, 290	MEMANTINE.....	725, 726
<i>Mabthera</i> (RO)		<i>Memantine generic</i> health(GQ).....	725, 726
.Highly Specialised Drugs Program (Private Hospital)921,		<i>Memantine RBX</i> (RA).....	725, 726
1049		<i>Memanxa</i> (RW).....	725, 726
.Highly Specialised Drugs Program (Public Hospital)1159,		<i>Menopur 1200</i> (FP).....	1629
1288		<i>Menopur 600</i> (FP).....	1629
MACITENTAN.....	878, 1115	<i>Mepilex 294100</i> (MH).....	1684
<i>Macrodantin</i> (PF).....	265	<i>Mepilex Ag</i> (MH).....	1683
MACROGOL-3350.....	52, 830	<i>Mepilex Border 295200</i> (MH).....	1683
MACROGOL-3350 + SODIUM CHLORIDE +		<i>Mepilex Border 295300</i> (MH).....	1683
BICARBONATE + POTASSIUM CHLORIDE.....	53, 830	<i>Mepilex Border Ag</i> (MH).....	1683
<i>Macrovic</i> (RF).....	53, 830	<i>Mepilex Lite 284000</i> (MH).....	1684
<i>Madopar 125</i> (RO).....	671	<i>Mepilex Lite 284100</i> (MH).....	1684
<i>Madopar 62.5</i> (RO).....	671	<i>Mepitac 298300</i> (MH).....	1695
<i>Madopar HBS</i> (RO).....	671	<i>Mepitac 298400</i> (MH).....	1695
<i>Madopar Rapid 125</i> (RO).....	671	<i>Mepitel 290510</i> (MH).....	1692
<i>Madopar Rapid 62.5</i> (RO).....	671	<i>Mepitel 290710</i> (MH).....	1692
<i>Madopar</i> (RO).....	671	MEPOLIZUMAB.....	1054, 1056, 1293, 1295
<i>Magicul 400</i> (AF).....	33	<i>Meprazol</i> (SZ).....	38, 39
<i>MagMin</i> (PBS)(BB).....	91	MERCAPTOPYRINE.....	287
<i>Magmin</i> (BB).....	1648	MESALAZINE.....	58, 59
MAGNESIUM ASPARTATE DIHYDRATE.....	91, 1648	<i>Mesasal</i> (AS).....	59
<i>Mag-Sup</i> (PP).....	91	MESNA.....	786
<i>Mag-Sup</i> (PP).....	1648	<i>Mestinon Timespan</i> (IA).....	727
<i>Malarone</i> (GK).....	733	<i>Mestinon</i> (IA).....	727
<i>Malean</i> (RW).....	132	<i>Metalyse</i> (BY).....	102
MANNITOL.....	1071, 1310	<i>Metamucil Natural Granular</i> (PY).....	1645
MARAVIROC.....	1336	<i>Metamucil Orange Smooth</i> (PY).....	1645
<i>Marevan</i> (FM).....	93	METEX XR 1000(RW).....	65
<i>Marevan</i> (FM).....	93	<i>Metex XR</i> (RW).....	65
<i>MassBiologics tetanus and diphtheria toxoids adsorbed</i> (CS)		METFORMIN.....	64
.....	24, 283	METFORMIN + GLIBENCLAMIDE.....	73
<i>Maxalt</i> (AL).....	654	<i>Metformin 500</i> (CR).....	65
<i>Maxamox</i> (SZ).....	237, 238	<i>Metformin 850</i> (CR).....	65
MAXATAN(RW).....	654	<i>Metformin AN</i> (EA).....	64, 65
<i>Maxidex</i> (NV).....	752	<i>Metformin generic</i> health (GQ).....	65
<i>Maxolon</i> (IA).....	25, 42, 43, 829	<i>Metformin generic</i> health 1000 (GQ).....	64
<i>Maxor</i> (AF).....	38, 39	<i>Metformin Ranbaxy 1000</i> (RA).....	64
<i>Mayne Pharma Doxycycline</i> (YT).....	234, 235, 236	<i>Metformin Ranbaxy</i> (RA).....	65

<i>Metformin Sandoz (SZ)</i> .....	64, 65	MILK POWDER LACTOSE INTOLERANCE FORMULA	809
<i>Metformin XR 500 APOTEX (GX)</i> .....	65	MILK POWDER SYNTHETIC LOW CALCIUM	809
<i>Metformin-GA(ED)</i> .....	64, 65	MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE.....	823
METHADONE		<i>Minax 100(AF)</i> .....	126
.NERVOUS SYSTEM.....	644	<i>Minax 50(AF)</i> .....	126
.Opiate Dependence Treatment Program	1632	<i>Minax XL (AF)</i> .....	125, 126
.Palliative Care	837, 838	<i>Minidiab(PF)</i> .....	67
<i>Methoblastin(PF)</i>		<i>Minipress(PF)</i> .....	119
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Minirin Melt(FP)</i> .....	225
AGENTS.....	286, 608	<i>Minirin Nasal Spray(FP)</i> .....	224, 225
<i>Methopt(QA)</i> .....	776, 777	<i>Minirin(FP)</i> .....	224
METHOTREXATE		<i>Minitran 10(IA)</i> .....	116
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Minitran 15(IA)</i> .....	117
AGENTS.....	286, 608	<i>Minitran 5(IA)</i> .....	116
<i>Methotrexate Accord(OD)</i> .....	286	MINOCYCLINE	236
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA		<i>Minomycin-50(QA)</i> .....	236
.....	853, 1090	MINOXIDIL	120
METHOXYFLURANE	25	<i>Mircera(RO)</i> .....	853, 1090
METHYL SALICYLATE.....	1663	<i>Mirena(BN)</i> .....	208
METHYLDOPA.....	118	<i>MIRTANZA(RF)</i> .....	711
METHYLNALTREXONE.....	831	MIRTAZAPINE	711
METHYLPHENIDATE.....	716, 717	<i>Mirtazapine AN (EA)</i> .....	711
<i>Methylpred(AL)</i> .....	228, 229	<i>Mirtazapine AN ODT (EA)</i> .....	711, 712
METHYLPREDNISOLONE		<i>Mirtazapine GH(GQ)</i> .....	711
.DERMATOLOGICALS.....	199, 200, 201	<i>Mirtazapine Sandoz (SZ)</i> .....	711
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		<i>Mirtazapine Sandoz ODT 15(SZ)</i> .....	711
HORMONES AND INSULINS.....	228, 229	<i>Mirtazapine Sandoz ODT 30(SZ)</i> .....	712
<i>Methylprednisolone Alphapharm (AF)</i> .....	228	<i>Mirtazapine Sandoz ODT 45(SZ)</i> .....	712
METOCLOPRAMIDE.....	25, 42, 829	<i>Mirtazon(RW)</i> .....	711
<i>Metoclopramide AN(EA)</i> .....	42	<i>Mistrom(ER)</i> .....	126
<i>Metoclopramide RBX (RA)</i> .....	42	<i>Mixtard 30/70 InnoLet (NI)</i> .....	63
<i>Metoprolol AN(EA)</i> .....	126	<i>Mixtard 30/70 Penfill 3 mL(NO)</i> .....	63
<i>Metoprolol RBX (RA)</i> .....	126	<i>Mixtard 50/50 Penfill 3 mL(NO)</i> .....	63
<i>Metoprolol Sandoz(SZ)</i> .....	126	<i>Mizart (AF)</i> .....	144
METOPROLOL SUCCINATE	125	<i>Mizart HCT 40/12.5 mg (AF)</i> .....	148
METOPROLOL TARTRATE	126	<i>Mizart HCT 80/12.5 mg (AF)</i> .....	148
<i>Metrogyl 200(AF)</i> .....	264	<i>Mizart HCT 80/25 mg (AF)</i> .....	149
<i>Metrogyl 400(AF)</i> .....	264	<i>MMA/PA Anamix infant(SB)</i> .....	813
<i>Metrol 100 (RW)</i> .....	126	<i>MMA/PA Anamix Junior(NU)</i> .....	813
<i>Metrol 50 (RW)</i> .....	126	<i>MMA/PA cooler 15(VF)</i> .....	813
<i>Metrol-XL 190(RW)</i> .....	126	<i>MMA/PA express 15(VF)</i> .....	813
<i>Metrol-XL 23.75(RW)</i> .....	125	<i>MMA/PA gel(VF)</i> .....	813
<i>Metrol-XL 47.5(RW)</i> .....	125	<i>Mobic(BY)</i> .....	612, 613
<i>Metrol-XL 95(RW)</i> .....	125	<i>Mobilis 10 (AF)</i> .....	614
METRONIDAZOLE.....	263, 264	<i>Mobilis 20 (AF)</i> .....	613
<i>Metronidazole Sandoz IV(SZ)</i> .....	264	<i>Mobilis D-10(AF)</i> .....	613
<i>Metronide 200 (AV)</i> .....	264	<i>Mobilis D-20(AF)</i> .....	613
<i>Metronide 400 (AV)</i> .....	264	MOCLOBEMIDE	708
<i>Mezavant(ZI)</i> .....	58	<i>Moclobemide AN (EA)</i> .....	708, 709
<i>Miacalcic 100(NV)</i> .....	233	<i>Moclobemide Sandoz(SZ)</i> .....	708, 709
MIANSERIN.....	710	<i>Modafin (RW)</i> .....	718
<i>Micardis Plus 40/12.5 mg(BY)</i> .....	148	MODAFINIL	717
<i>Micardis Plus 80/12.5 mg(BY)</i> .....	149	<i>Modafinil AN(EA)</i> .....	718
<i>Micardis Plus 80/25 mg(BY)</i> .....	149	<i>Modafinil Mylan (AF)</i> .....	718
<i>Micardis(BY)</i> .....	144	<i>Modafinil Sandoz(SZ)</i> .....	718
<i>Micolette(AE)</i> .....	54, 831, 1645	<i>Modavigil (TB)</i> .....	718
MICONAZOLE.....	190, 1651	MODIFIED LONG CHAIN AMYLOPECTIN	803
<i>Microdacyn(TF)</i> .....	1694	<i>Moduretic(AS)</i> .....	122
<i>Microgynon 30 ED(BN)</i> .....	210	<i>Mogadon(IA)</i>	
<i>Microgynon 50 ED(BN)</i> .....	209	.Palliative Care.....	841
<i>Microlut 28(BN)</i> .....	210	<i>Mogadon(IA)</i>	
<i>Micronelle 30 ED(TX)</i> .....	210	.NERVOUS SYSTEM.....	658, 699, 700
MIDAZOLAM.....	25	<i>Mohexal (HX)</i> .....	709
MIFEPRISTONE (&) MISOPROSTOL	221	<i>Molaxole (HM)</i> .....	53, 830
<i>Milivin OD 15(DO)</i> .....	711	<i>Momasone(QA)</i> .....	202, 203, 204
<i>Milivin OD 30(DO)</i> .....	711	MOMETASONE	201, 202, 203, 204, 1655
<i>Milivin OD 45(DO)</i> .....	712	<i>Momex SR 10(RW)</i> .....	636
MILK POWDER LACTOSE FREE FORMULA	809	<i>Momex SR 100(RW)</i> .....	637
MILK POWDER LACTOSE FREE FORMULA		<i>Momex SR 30(RW)</i> .....	636
PREDIGESTED.....	809		

Momex SR 60(RW)	637	Myocrisin(SW)	618
Monace 10(AF)	132	Mysoline(LM)	657
Monace 20(AF)	132	NADROPARIN	96, 97
Monodur 120 mg(PM)	117	NAFARELIN	225, 1629
Monodur 60 mg(PM)	117	NALOXONE	25, 783
Monofeme 28(FZ)	210	Naloxone Hydrochloride (DBL)(PF)	25, 783, 784
Monogen(SB)	803	Naloxone Juno (JU)	25, 783, 784
MONTELUKAST	748	NALTREXONE	730
Montelukast AN(EA)	748, 749	Naltrexone GH (GQ)	730
Montelukast GH (GQ)	748, 749	NANDROLONE DECANOATE	91
Montelukast Sandoz 4(SZ)	748	NAPHAZOLINE	1672
Montelukast Sandoz 5(SZ)	749	NAPHAZOLINE + ANTAZOLINE	1672
MORPHINE	25, 633, 634, 635, 637, 833, 1665	Naprosyn SR1000(IX)	615, 616, 833
Morphine Juno(JU)	25, 633, 634, 635	Naprosyn SR750(IX)	615, 616, 833
Morphine MR AN (EA)	636, 637	Naprosyn(IX)	615, 616, 833
MORPHINE MR APOTEX(TX)	636, 637	NAPROXEN	615, 616, 832, 833
Morphine MR Mylan (AF)	636, 637	Naramig(AS)	653, 654
Motilium(JC)	42	NARATRIPTAN	653
Movalis 15 (RW)	613	Nardil(LM)	708
Movalis 15(RW)	612	NATALIZUMAB	947, 1185
Movalis 7.5 (RW)	612	Natrilix SR(SE)	120
Movalis 7.5(RW)	613	Natrilix(SE)	120
Movapo PFS(TD)	1053, 1292	Navelbine(FB)	288
Movapo(TD)	1052, 1053, 1292	Nebilet(FK)	126, 127
Movicol Liquid(NE)	53, 831	NEBIVOLOL	126
Movicol(NE)	53, 830	NEDOCROMIL	746
Movox 100(AF)	706	Neo-B12 (PF)	112
Movox 50(AL)	706	Neo-B12(PF)	1649
Moxicam 15 (AF)	612	Neocate Advance Vanilla(SB)	790, 791, 792
Moxicam 7.5 (AF)	613	Neocate Advance(SB)	791, 792
Moxicam(AF)	612, 613	Neocate Gold(SB)	795, 796, 797
Moxiclav Duo 500/125(QA)	244, 245	Neocate Junior(SB)	807, 809
Moxiclav Duo Forte 875/125(QA)	243, 244	Neocate LCP(SB)	793, 794
MOXONIDINE	119	Neo-Mercazole (GH)	232
Mozobil(GZ)	931, 1169	Neoral 10(NV)	606, 1038, 1277
MS Contin Suspension 100 mg(MF)	637	Neoral 100 (NV)	607, 1038, 1277
MS Contin Suspension 20 mg(MF)	637	Neoral 25 (NV)	606, 1038, 1277
MS Contin Suspension 200 mg(MF)	634	Neoral 50 (NV)	607, 1038, 1277
MS Contin Suspension 30 mg(MF)	636	Neoral(NV)	606, 1038, 1277
MS Contin Suspension 60 mg(MF)	636	NeoRecormon(RO)	852, 1089
MS Contin(MF)	634, 636, 637, 833, 1665	Neotigason(UA)	193
MS Mono(MF)	636, 637	Nesina Met 12.5/1000(TK)	67
MS-2 Step(XH)	222	Nesina Met 12.5/500(TK)	68
MSUD AID III(SB)	817	Nesina Met 12.5/850(TK)	67
MSUD amino5(VF)	818	Nesina(TK)	80
MSUD Anamix infant(SB)	817	NETUPIANT + PALONOSETRON	43
MSUD Anamix Junior LQ(SB)	817	Neulactil(SW)	678
MSUD Anamix Junior(SB)	817	Neulasta(AN)	929, 1167
MSUD cooler 10(VF)	817	Neupogen(AN)	924, 1162
MSUD cooler 15(VF)	816	Neupro(UC)	676
MSUD cooler 20(VF)	816	Neuroccord (CR)	652, 653
MSUD express 15(VF)	816	Neurontin (PF)	
MSUD express 20(VF)	816	.Repatriation Pharmaceutical Benefits Scheme	1667
MSUD gel(VF)	817	Neurontin (PF)	
MSUD Lophlex LQ 20(SB)	817	.NERVOUS SYSTEM	662, 663
MSUD Maxamum(SB)	817	Neurontin(PF)	
MUPIROICIN		.Repatriation Pharmaceutical Benefits Scheme	1666, 1667
.Repatriation Pharmaceutical Benefits Scheme	1654	Neurontin(PF)	
.RESPIRATORY SYSTEM	736	.NERVOUS SYSTEM	662, 663
Murelax(RW)	698, 699, 840	NEVIRAPINE	1329
Mycobutin(PF)	912, 1150	Nevirapine Alphapharm(AF)	1330
Myconail(AE)	1651	Nevirapine XR APOTEX(TX)	1329
MYCOPHENOLATE	366, 367, 945, 946, 1184, 1185	Nexavar(BN)	332, 333
Mycophenolate AN (EA)	366, 946, 1184	Nexazole (RW)	35, 36
Mycophenolate Sandoz(SZ)	366, 367, 946, 1184, 1185	Nexcare Durable Cloth First Aid Tape 799(MM)	1695
Mycostatin Oral Drops(QA)	1643	Nexcare Gentle Paper First Aid Tape 789(MM)	1694
Mycostatin(FM)	190, 1650	Nexcare Tegaderm Transparent H1624(MM)	1681
Myfortic(NV)	367, 946, 1185	Nexcare Tegaderm Transparent H1626(MM)	1681
Mylanta Double Strength(JT)	1643	Nexium Hp7(AP)	41
Myleran(AS)	283		

<i>Nexium</i> (AP) .....	35, 36	<i>NovoMix 30 Penfill 3 mL</i> (NO) .....	63
<i>Nexole</i> (RF) .....	35, 36	<i>NovoRapid FlexPen</i> (NF) .....	62
<i>Nicabate CQ 14</i> (GC) .....	1669	<i>NovoRapid Penfill 3 mL</i> (NO) .....	62
<i>Nicabate CQ 21</i> (GC) .....	1670	<i>NovoRapid</i> (NO) .....	62
<i>Nicabate P</i> (GC) .....	729	<i>Noxafil</i> (MK) .....	268, 269
NICORANDIL .....	117	<i>Noxicid Caps</i> (AL) .....	35, 36, 37
<i>nicorette 16hr Invisipatch</i> (JT) .....	729	<i>Nplate</i> (AN) .....	849, 1086
<i>Nicorette Patch</i> (JT) .....	1669	<i>Nucala</i> (GK) .....	1056, 1058, 1295, 1297
NICOTINE .....	728, 1669	<i>Nuelin</i> (IA) .....	748
<i>Nicotinell Step 1</i> (ON) .....	728	<i>Nuelin-SR 200</i> (IA) .....	748
<i>Nicotinell Step 2</i> (ON) .....	728	<i>Nuelin-SR 250</i> (IA) .....	748
<i>Nicotinell Step 3</i> (ON) .....	728	<i>Nuelin-SR 300</i> (IA) .....	747
<i>Nidem</i> (RW) .....	66	<i>Nufloxib</i> (AF) .....	262
NIFEDIPINE .....	130	<i>Nu-Gel 2497</i> (KI) .....	1692
NILOTINIB .....	319, 321	<i>Nupentin 100</i> (AF)	
<i>Nilstat</i> (QA)		Repatriation Pharmaceutical Benefits Scheme .....	1666
Repatriation Pharmaceutical Benefits Scheme .....	1657	<i>Nupentin 100</i> (AF)	
<i>Nilstat</i> (QA)		NERVOUS SYSTEM .....	662
ALIMENTARY TRACT AND METABOLISM .....	54, 55	<i>Nupentin 300</i> (AF)	
NILUTAMIDE .....	351	NERVOUS SYSTEM .....	663
NINTEDANIB .....	323	<i>Nupentin 300</i> (AF)	
NITRAZEPAM		Repatriation Pharmaceutical Benefits Scheme .....	1667
NERVOUS SYSTEM .....	658, 699	<i>Nupentin 400</i> (AF)	
Palliative Care .....	841	NERVOUS SYSTEM .....	662
<i>Nitro-Dur 10</i> (MK) .....	116	<i>Nupentin 400</i> (AF)	
<i>Nitro-Dur 15</i> (MK) .....	117	Repatriation Pharmaceutical Benefits Scheme .....	1667
<i>Nitro-Dur 5</i> (MK) .....	116	<i>Nupentin Tabs</i> (AF)	
NITROFURANTOIN .....	265	Repatriation Pharmaceutical Benefits Scheme .....	1667
<i>Nitrolingual Pumpspray</i> (SW) .....	24, 117	<i>Nupentin Tabs</i> (AF)	
<i>Nitrostat</i> (PF) .....	116, 117	Repatriation Pharmaceutical Benefits Scheme .....	1667
<i>Nivestim</i> (PF) .....	924, 1162	<i>Nupentin Tabs</i> (AF)	
<i>Nizac</i> (RF) .....	34	NERVOUS SYSTEM .....	662, 663
NIZATIDINE .....	34	<i>Nutrini Peptisorb Energy</i> (NU) .....	789
<i>Nizoral 1%</i> (JT) .....	190	<i>Nutrini Peptisorb</i> (SB) .....	803
<i>Nizoral 2% Cream</i> (JT) .....	190	<i>NutropinAq</i> (IS) .....	1381, 1466, 1559
<i>Nizoral 2%</i> (JT) .....	190	<i>Nuvigil</i> (TB) .....	714
<i>Nolvadex-D</i> (AP) .....	348	<i>Nyogel</i> (AS) .....	759
<i>Nolvadex-D</i> (AP) .....	347	NYSTATIN	
<i>Nordette 28</i> (PF) .....	210	ALIMENTARY TRACT AND METABOLISM .....	54
<i>Nordip</i> (AF) .....	128	DERMATOLOGICALS .....	190
<i>Norditropin FlexPro</i> (NO) .....	1380, 1381, 1466, 1559	Repatriation Pharmaceutical Benefits Scheme .....	1643, 1650, 1657
<i>Norditropin SimpleXx</i> (NO) .....	1380, 1381, 1466, 1559	<i>O.R.S.</i> (AS) .....	56
NORETHISTERONE		OCRIPLASMIN .....	778
GENITO URINARY SYSTEM AND SEX HORMONES		OCTREOTIDE .....	908, 909, 1145, 1146
.....	211, 216	<i>Octreotide</i> (SUN)(RA) .....	909, 910, 1147
NORETHISTERONE + ETHINYLOESTRADIOL .....	210	<i>Octreotide MaxRx</i> (GQ)	
NORETHISTERONE + MESTRANOL .....	210	Highly Specialised Drugs Program (Private Hospital) .....	909
NORETHISTERONE ACETATE + OESTRADIOL (&)		Highly Specialised Drugs Program (Public Hospital) .....	1147
OESTRADIOL .....	217	<i>Ocuflox</i> (AG) .....	752
NORFLOXACIN .....	261	<i>Odaplix SR</i> (AF) .....	120
<i>Noriday 28 Day</i> (PF) .....	211	<i>Odefsey</i> (GI) .....	1332
<i>Norimin 28 Day</i> (FZ) .....	210	OESTRADIOL .....	214
<i>Norimin-1 28 Day</i> (FZ) .....	210	OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE	
<i>Norinyl-1/28</i> (PF) .....	210	.....	217
<i>Normacol Plus</i> (NE) .....	52, 830, 1645	OESTRADIOL + DYDROGESTERONE .....	216
<i>Normison</i> (QA) .....	700, 701, 841	OESTRADIOL + NORETHISTERONE ACETATE .....	217
<i>Norprolac</i> (FP) .....	209	OESTRIOL .....	215
<i>Norspan</i> (MF) .....	645, 838, 839	<i>Ofev</i> (BY) .....	324
NORTRIPTYLINE .....	703	OFLOXACIN .....	752
<i>NortriTABS 10 mg</i> (GH) .....	703	<i>Olanzacor 10</i> (CR) .....	683
<i>NortriTABS 25 mg</i> (GH) .....	703	<i>Olanzacor 2.5</i> (CR) .....	681
<i>Norvapine</i> (ED) .....	128	<i>Olanzacor 5</i> (CR) .....	682
<i>Norvasc</i> (PF) .....	128, 129	<i>Olanzacor 7.5</i> (CR) .....	682
<i>Norvir</i> (VE) .....	1322	OLANZAPINE .....	681, 682, 683, 684, 685
<i>Noten</i> (AF) .....	124	<i>Olanzapine AN</i> (EA) .....	681, 682, 683
<i>Novacodone</i> (HX) .....	639, 640	<i>Olanzapine AN ODT</i> (EA) .....	683, 684, 685
<i>Novasone</i> (AF) .....	202, 203, 204	<i>Olanzapine generichealth 10</i> (GQ) .....	683
<i>Novatin</i> (TX) .....	193	<i>Olanzapine generichealth 2.5</i> (GQ) .....	681
<i>Novicrit</i> (SZ) .....	852, 853, 1089, 1090	<i>Olanzapine generichealth 5</i> (GQ) .....	681
<i>NovoMix 30 FlexPen</i> (NF) .....	63		

Olanzapine generichealth 7.5(GQ)	682	Optifresh Plus(PP)	774
Olanzapine ODT generichealth 10 (GQ)	684	Optifresh Tears(PP)	774
Olanzapine ODT generichealth 5 (GQ)	683	Optive(AG)	775
Olanzapine ODT-DRLA(RZ)	683, 684	Orabase(QA)	1652
Olanzapine RBX (RA)	681, 682, 683	Oratane (RF)	206
Olanzapine Sandoz ODT 10(SZ)	684	Oratane(RF)	206
Olanzapine Sandoz ODT 15(SZ)	684	Ordine 10(MF)	635, 638
Olanzapine Sandoz ODT 20(SZ)	685	Ordine 2(MF)	635, 638
Olanzapine Sandoz ODT 5(SZ)	683	Ordine 5(MF)	635, 637
Olanzapine Sandoz(SZ)	681, 682, 683	Orencia ClickJect(BQ)	360, 364
Olanzapine-DRLA(RZ)	681, 682, 683	Orencia(BQ)	360, 364, 936, 1175
OLAPARIB	339, 340	Orgalutran(MK)	1630
OLMERTAN (RW)	143, 144	Orion Temozolomide (ON)	284, 285, 286
OLMERTAN COMBI 20/12.5 (RW)	148	Oripro(ON)	1626
OLMERTAN COMBI 40/12.5 (RW)	148	ORLISTAT	1646
OLMERTAN COMBI 40/25 (RW)	148	Oroxine(QA)	231
Olmesartan - MYL (AF)	143, 144	Orudis SR 200(SW)	614, 615
OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE	152	Oruvail SR(AV)	614, 615
Olmesartan AN(EA)	143, 144	OsmoLax(KY)	53, 830
Olmesartan HCT - MYL 20/12.5 (AF)	148	Ospolot(PL)	668
Olmesartan HCT - MYL 40/12.5 (AF)	148	Osteomol 665 Paracetamol (CR)	651, 839
Olmesartan HCT - MYL 40/25 (AF)	148	Osteomol 665 Paracetamol(CR)	651, 839, 1666
Olmesartan HCT AN 20/12.5(EA)	148	Osteovan (SZ)	623, 624
Olmesartan HCT AN 40/12.5(EA)	148	Ostira(PF)	624
Olmesartan HCT AN 40/25(EA)	148	Otocomb Otic(FM)	782
OLMESARTAN MEDOXOMIL	143	Otodex(AV)	782
OLMESARTAN MEDOXOMIL + AMLODIPINE	150	Ovestin Ovula(AS)	216
OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE	147	Ovestin(AS)	216
Olmesartan Sandoz(SZ)	143, 144	Ovidrel(SG)	1627
Olmesartan/Amlodipine - MYL 20/5(AF)	150	OXAZEPAM	698, 840
Olmesartan/Amlodipine - MYL 40/10(AF)	151	OXCARBAZEPINE	659
Olmesartan/Amlodipine - MYL 40/5(AF)	151	Oxis Turbuhaler(AP)	736
Olmesartan/HCT Sandoz(SZ)	148	OXPRENOLOL	123
Olmetec Plus (MK)	148	OXYBUTYNIN	222
Olmetec(MK)	143, 144	Oxybutynin Sandoz (SZ)	222
OLSALAZINE	60	OXYCODONE	638, 639, 640
OMALIZUMAB .1058, 1059, 1060, 1066, 1297, 1298, 1299, 1305		OXYCODONE + NALOXONE	640
Omegapharm Pty Ltd(OE)	252	Oxycodone Aspen(FM)	638, 639
Omepral (ZA)	38, 39	Oxycodone Sandoz (SZ)	639, 640
OMEPRAZOLE	38	OxyContin(MF)	639, 640
Omeprazole AN (EA)	38, 39	OXYMETAZOLINE	1670
Omeprazole generichealth(GQ)	38, 39	OxyNorm Liquid 1mg/mL(MF)	638, 639
Omeprazole Sandoz(HX)	38, 39	OxyNorm(MF)	638, 639
Omeprazole Sandoz(SZ)	38, 39	OXYTOCIN	25
Omnitrope Surepal 10(SZ)	1356, 1448, 1520	Oxytocin Sandoz(SZ)	25
Omnitrope Surepal 15(SZ)	1357, 1448, 1521	Oxytrol(GN)	222
Omnitrope Surepal 5(SZ)	1357, 1448, 1520	Ozcef(RA)	249
Omnitrope(SZ)	1356, 1448, 1520	Ozidal (RA)	692, 693, 695
Onbrez(NV)	736	Ozidal(RA)	694, 696
OncoTICE(MK)	357	Ozin 10 (DO)	683
ONDANSETRON	44, 45, 46, 47	Ozin 2.5 (DO)	681
Ondansetron Alphapharm(AF)	45, 46	Ozin 5 (DO)	682
Ondansetron AN (EA)	44, 45	Ozin 7.5 (DO)	682
Ondansetron AN ODT(EA)	46, 47	Ozin ODT 10 (DO)	684
Ondansetron ODT GH(GQ)	46, 47	Ozin ODT 15 (DO)	684
Ondansetron ODT-DRLA (RZ)	46, 47	Ozin ODT 20 (DO)	685
Ondansetron SZ (HX)	44, 45	Ozin ODT 5 (DO)	683
Ondansetron SZ ODT (HX)	46, 47	Ozlodip (RA)	128
Ondansetron-DRLA(RZ)	44, 45	Ozmep (ZP)	38, 39
Onglyza(AP)	82	Ozole (RA)	265, 266
Onsetron (ZP)	45, 46	Ozole(RA)	266
Onsetron 4(ZP)	45	Ozpan (RA)	39, 40
Onsetron 8(ZP)	45	Ozpan(RA)	40
Op-Site Flexigril 4629(SN)	1681	Ozurdex(AG)	754
Opsumit(AT)	883, 1120	Ozvir (RA)	273
Opticrom(SW)	763	PAA (IA)	773
Optifresh eye gel(PP)	773	Pacrolim(AF)	607, 1039, 1278
		Paediatric Seravit(SB)	826
		Palaxia SR(CS)	646, 647
		PALIPERIDONE	690, 691

PALONOSETRON.....	47	<i>Penthrox(DV)</i> .....	25
PAMIDRONATE DISODIUM.....	622, 1051, 1290	<i>Peptamen Junior(NT)</i> .....	803
<i>Pamisol(PF)</i> .....	622, 1051, 1290	<i>Pepzan(ED)</i> .....	33, 34
<i>Panadeine Forte(SW)</i> .....	645, 646	PERAMPANEL.....	667
<i>Panadol(GC)</i> .....	839	<i>Pergoveris(SG)</i> .....	1628
<i>Panafacort(AS)</i> .....	229, 230	PERHEXILINE.....	118
<i>Panafacortelone(AS)</i> .....	229	<i>Periactin(AS)</i> .....	656
<i>Panamax (SW)</i> .....	650, 651, 1666	PERICYAZINE.....	678
<i>Panamax 240 Elixir(SW)</i> .....	650, 1666	<i>Perindo (AF)</i> .....	134, 135
<i>Panamax Co. 40(SW)</i> .....	1665	<i>Perindo Combi 4/1.25(AF)</i> .....	138
<i>Panamax(SW)</i> .....	650	PERINDOPRIL.....	133, 134
PANCREATIC EXTRACT.....	61	PERINDOPRIL + AMLODIPINE.....	139
PANCRELIPASE.....	61, 62	PERINDOPRIL + INDAPAMIDE.....	138
PANTHENOL.....	1657	<i>Perindopril Actavis 2(EA)</i> .....	134
<i>Panthron (ER)</i> .....	40	<i>Perindopril Actavis 4(ED)</i> .....	134
<i>Panthron(ER)</i> .....	39, 40	<i>Perindopril Actavis 8(ED)</i> .....	135
<i>Panto (TK)</i> .....	39, 40	<i>Perindopril AN (EF)</i> .....	134, 135
<i>Panto(TK)</i> .....	40	<i>Perindopril and Indapamide AN 4/1.25(EF)</i> .....	138
<i>Pantofast 20 (RZ)</i> .....	40	<i>Perindopril Combi Actavis 4/1.25 (ED)</i> .....	138
<i>Pantofast 40(RZ)</i> .....	39, 40	<i>Perindopril generichealth(GQ)</i> .....	134, 135
PANTOPRAZOLE.....	39	<i>Perindopril/ Indapamide GH 4/1.25(GQ)</i> .....	138
<i>Pantoprazole Actavis (ED)</i> .....	39, 40	PERMETHRIN.....	735
<i>Pantoprazole AN(EA)</i> .....	39, 40	<i>Persantin SR(BY)</i> .....	100
<i>Pantoprazole GH (GQ)</i> .....	39, 40	<i>Petrus Bisacodyl Suppositories(PP)</i> .....	51, 52, 829, 830, 1644
<i>Pantoprazole Sandoz(SZ)</i> .....	39, 40	<i>Petrus Pharmaceuticals Pty Ltd(PP)</i> .....	1645
<i>Panzyltrat 25000(TM)</i> .....	62	<i>Pexsig(QA)</i> .....	118
PAPER WASP VENOM.....	783	<i>Pfizer Australia Pty Ltd(PF)</i>	
PARACETAMOL.....	650, 651, 839, 1666	.Prescriber Bag.....	23, 25
<i>Paracetamol (Sandoz)(SZ)</i> .....	650, 651, 1666	<i>Pfizer Australia Pty Ltd(PF)</i>	
PARACETAMOL + CODEINE.....	645, 646, 1665	.ALIMENTARY TRACT AND METABOLISM.....	42
<i>Paracetamol/Codeine GH 500/30(GQ)</i> .....	645, 646	<i>Pfizer Australia Pty Ltd(PF)</i>	
PARAFFIN.....	778, 779	.ALIMENTARY TRACT AND METABOLISM.....	42
<i>Paralgin (OW)</i> .....	650, 651, 1666	<i>Pfizer Australia Pty Ltd(PF)</i>	
<i>Parapane(AF)</i> .....	650, 651, 1666	.BLOOD AND BLOOD FORMING ORGANS.....	96
<i>Parbezol (RW)</i> .....	41	<i>Pfizer Australia Pty Ltd(PF)</i>	
<i>Parbezol(RW)</i> .....	40, 41	.ANTIINFECTIVES FOR SYSTEMIC USE.....	258
<i>Pariet(JC)</i> .....	41	<i>Pfizer Australia Pty Ltd(PF)</i>	
PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR.....	280, 916, 1153	.ANTIINFECTIVES FOR SYSTEMIC USE.....	259
PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN.....	281, 916, 1154	<i>Pharmacor Amisulpride (CR)</i> .....	688
<i>Parlodel(SZ)</i>		<i>Pharmacor Amisulpride(CR)</i> .....	688, 689
.GENITO URINARY SYSTEM AND SEX HORMONES		<i>Pharmacor Amlodipine(CR)</i> .....	128, 129
.....	208	<i>Pharmacor Atorvastatin(CR)</i> .....	153, 154, 155
.NERVOUS SYSTEM.....	674	<i>Pharmacor Cefuroxime(CR)</i> .....	250
<i>Parnate(GH)</i> .....	708	<i>Pharmacor Citalo 20(CR)</i> .....	703
PAROXETINE.....	707	<i>Pharmacor Donepezil 10 (CR)</i> .....	719, 721
<i>Paroxetine AN(EA)</i> .....	707	<i>Pharmacor Duloxetine 30 (CR)</i> .....	710
<i>Paroxetine GH (GQ)</i> .....	707	<i>Pharmacor Duloxetine 60 (CR)</i> .....	710
<i>Paroxetine Sandoz(SZ)</i> .....	707	<i>Pharmacor Escitalopram 10 (CR)</i> .....	704
<i>Parzol 10(ZP)</i> .....	41	<i>Pharmacor Escitalopram 20 (CR)</i> .....	704
<i>Parzol 20 (ZP)</i> .....	40, 41	<i>Pharmacor Esomeprazole(CR)</i> .....	35, 36
PASIREOTIDE.....	910, 1147	<i>Pharmacor Finasteride 5(CR)</i> .....	1661
<i>Paxam 0.5(AF)</i> .....	658, 839	<i>Pharmacor Gabapentin 600 (CR)</i>	
<i>Paxam 2(AF)</i> .....	658, 840	.NERVOUS SYSTEM.....	662
<i>Paxtine (AF)</i> .....	707	<i>Pharmacor Gabapentin 800 (CR)</i>	
PAZOPANIB.....	324, 325, 326	.NERVOUS SYSTEM.....	663
<i>Peg 7420(MM)</i> .....	1675	<i>Pharmacor Letrozole 2.5(CR)</i> .....	353
<i>Peg 7422(MM)</i> .....	1675	<i>Pharmacor Meloxicam 15(CR)</i> .....	612
<i>Peg 7423(MM)</i> .....	1675	<i>Pharmacor Meloxicam 7.5(CR)</i> .....	613
<i>Peg 7425(MM)</i> .....	1675	<i>Pharmacor Metformin 1000(CR)</i> .....	64
<i>Pegasys(RO)</i> .....	356, 930, 931, 1169, 1338, 1339	<i>Pharmacor Mycophenolate 250 (CR)</i> .....	367, 946, 1185
PEGFILGRASTIM.....	927, 1165	<i>Pharmacor Mycophenolate 500 (CR)</i> .....	366, 946, 1184
PEGINTERFERON ALFA-2A.....	356, 930, 1168, 1169, 1338	<i>Pharmacor Olmesartan 20 (CR)</i> .....	144
PEGINTERFERON BETA-1A.....	356	<i>Pharmacor Olmesartan 40 (CR)</i> .....	143
PEGVISOMANT.....	904, 905, 1142	<i>Pharmacor Omeprazole 20(CR)</i> .....	38, 39
<i>Pemzo (RW)</i> .....	38, 39	<i>Pharmacor Quetiapine 100(CR)</i> .....	686
PENICILLAMINE.....	618	<i>Pharmacor Quetiapine 200(CR)</i> .....	687
<i>Pentasa(FP)</i> .....	58, 59, 60	<i>Pharmacor Quetiapine 25(CR)</i> .....	688
PENTASTARCH + SODIUM CHLORIDE.....	112	<i>Pharmacor Quetiapine 300(CR)</i> .....	687
		<i>Pharmacor Riluzole (CR)</i> .....	732
		<i>Pharmacor Sumatriptan 50 (CR)</i> .....	655

<i>Pharmacor Tacrolimus 0.5 (CR)</i> .....	607, 1039, 1278	<i>PKU Cooler 20(VF)</i> .....	815
<i>Pharmacor Tacrolimus 1 (CR)</i> .....	607, 1039, 1278	<i>PKU Easy Microtabs(OH)</i> .....	810
<i>Pharmacor Tacrolimus 5 (CR)</i> .....	607, 1039, 1278	<i>PKU Easy Shake &amp; Go(OH)</i> .....	810
<i>Pharmacor Telmisartan 40(CR)</i> .....	144	<i>PKU Easy(OH)</i> .....	824
<i>Pharmacor Telmisartan 80(CR)</i> .....	144	<i>PKU express 15(VF)</i> .....	815
<i>Pharmacy Action Anti-Fungal Cream(GQ)</i> .....	1651	<i>PKU express 20(VF)</i> .....	814
<i>Pharmacy Action Anti-Fungal Nail Treatment(GQ)</i> .....	1651	<i>PKU gel(VF)</i> .....	813
<i>Pharmacy Action Cetrelief(GQ)</i> .....	1671	<i>PKU Glytactin RTD 10(QH)</i> .....	821
<i>Pharmacy Action Diarrhoea Relief(GQ)</i> .....	1646	<i>PKU Glytactin RTD 15(QH)</i> .....	821
<i>Pharmacy Action FemCream (GQ)</i> .....	1658	<i>PKU Go(OH)</i> .....	810
<i>Pharmacy Action Fexorelief 120(GQ)</i> .....	1672	<i>PKU Lophlex LQ 10(SB)</i> .....	814
<i>Pharmacy Action Laxative with Senna(GQ)</i> .....	1644	<i>PKU Lophlex LQ 20(SB)</i> .....	814
<i>Pharmacy Action Lorastyne(GQ)</i> .....	1672	<i>PKU Lophlex Sensation 20(SB)</i> .....	814
<i>Pharmacy Action Low Dose Aspirin (GQ)</i> .....	1648	<i>PKU Lophlex(SB)</i> .....	814
<i>Pharmacy Action Nystatin Oral Drops(GQ)</i> .....	1643	<i>PKU Restore(QH)</i> .....	822
<i>Pharmacy Action Paracetamol Plus Codeine(GQ)</i> .....	1665	<i>PKU Sphere(VF)</i> .....	822
<i>Pharmacy Action Pharmsil (GQ)</i> .....	1651	<i>PKU squeezie(VF)</i> .....	815
<i>Pharmacy Action Sinus &amp; Nasal Decongestant Relief(GQ)</i> .....	1671	<i>Placil (AF)</i> .....	702
<i>Pharmacy Action Worm Treatment(GQ)</i> .....	1670	<i>Plaqacide(OB)</i> .....	1643
<i>Pharmacy Choice Finasteride (RI)</i> .....	1661	<i>Plaquenil(SW)</i> .....	618
<i>Phebra Naproxen Suspension(PL)</i> .....	615, 832	<i>Plavacor 75 (CR)</i> .....	99
PHENELZINE .....	708	<i>Plavix (SW)</i> .....	98
<i>Phenobarb(RW)</i> .....	656	<i>Plavix(SW)</i> .....	99, 1649
PHENOBARBITONE .....	656	<i>Plegridy(BD)</i> .....	356, 357
PHENOXYBENZAMINE .....		<i>Plendil ER(GX)</i> .....	129
.CARDIOVASCULAR SYSTEM .....	123	PLERIXAFOR.....	931, 1169
.GENITO URINARY SYSTEM AND SEX HORMONES .....	222	<i>Plidogrel (RF)</i> .....	99
PHENOXYMETHYLPENICILLIN .....	239, 240	<i>Plidogrel(RF)</i> .....	98
<i>Phenoxymethylpenicillin-AFT(AE)</i> .....	239, 240	PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES .....	282
<i>Phenylalanine 50(VF)</i> .....	823	<i>Pneumovax 23(CS)</i> .....	282, 283
PHENYLALANINE WITH CARBOHYDRATE .....	823	PODOPHYLLOTOXIN .....	1654
PHENYTOIN.....	657	<i>Poly Gel(NV)</i> .....	773
<i>Phlexy-10 Drink Mix(SB)</i> .....	818	<i>Poly Visc(NV)</i> .....	778, 779
<i>Phlexy-10(SB)</i> .....	818	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL .....	779, 780
<i>Phlexy-Vits(SB)</i> .....	825	POLYLACTIC ACID.....	786, 787
PHOLCODINE .....	1671	<i>Polytar(GK)</i> .....	1656
<i>Phosphate Sandoz(PL)</i> .....	786	<i>Poly-Tears(NM)</i> .....	776
PHOSPHORUS .....	786	POLYVINYL ALCOHOL .....	780, 781
<i>Physeptone(QA)</i> .....	644	POMALIDOMIDE.....	1044, 1282
<i>Physiotens(GO)</i> .....	119	<i>Pomalyst(CJ)</i> .....	1045, 1284
PHYTOMENADIONE .....	26	PONATINIB .....	327, 329
<i>Piax (AF)</i> .....	1649	<i>Ponstan(PF)</i> .....	617
<i>Piax Plus Aspirin(AF)</i> .....	100	POSACONAZOLE .....	268, 269
<i>Piax(AF)</i> .....	98, 99	POTASSIUM CHLORIDE .....	91
<i>Picato(LO)</i> .....	1654	POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE .....	91
PILOCARPINE.....	756	POVIDONE-IODINE .....	
PIMECROLIMUS .....	206	.Repatriation Pharmaceutical Benefits Scheme .....	1655, 1694
PINDOLOL.....	123	<i>Pradaxa(BY)</i> .....	103, 104
PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE .....	1653	<i>Pramin(AF)</i> .....	42
<i>Pinetarsol(EO)</i> .....	1653	PRAMIPEXOLE .....	674, 675
PIOGLITAZONE .....	78	<i>Pramipexole AN (EA)</i> .....	674
<i>Pioglitazone AN (EA)</i> .....	79	<i>Pramipexole GH(GQ)</i> .....	674
<i>Pioglitazone Sandoz(SZ)</i> .....	79	<i>Pramipexole XR GP (AF)</i> .....	675
PIRFENIDONE .....	608	PRASUGREL .....	101
PIROXICAM.....	613	<i>Pravachol(RW)</i> .....	156, 157, 158
<i>Pizaccord (RA)</i> .....	79	PRAVASTATIN .....	156, 157
PIZOTIFEN .....	656	<i>Pravastatin AN(EA)</i> .....	156, 157, 158
<i>PKU Air 15(VF)</i> .....	814	<i>Pravastatin generichealth (GQ)</i> .....	156, 157, 158
<i>PKU Air 20(VF)</i> .....	814	<i>Pravastatin Sandoz(SZ)</i> .....	156, 157, 158
<i>PKU Anamix First Spoon(SB)</i> .....	818	PRAZQUANTEL .....	734
<i>PKU Anamix infant(SB)</i> .....	818	PRAZOSIN .....	119
<i>PKU Anamix Junior LQ(SB)</i> .....	814	<i>PredMix(LN)</i> .....	229
<i>PKU Anamix Junior(SB)</i> .....	815	<i>Prednefrin Forte(AG)</i> .....	755
<i>PKU Baby(OH)</i> .....	810	PREDNISOLONE .....	229
<i>PKU Bettermilk Lite(QH)</i> .....	822	PREDNISOLONE ACETATE + PHENYLEPHRINE.....	754, 755
<i>PKU Cooler 10(VF)</i> .....	813	PREDNISOLONE SODIUM PHOSPHATE .....	
<i>PKU Cooler 15(VF)</i> .....	814		

.ALIMENTARY TRACT AND METABOLISM .....	57	PROPYLTHIOURACIL .....	231
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		<i>Proscar (MK)</i> .....	1661
HORMONES AND INSULINS .....	229	<i>Protaphane (NO)</i> .....	63
PREDNISON .....	229	<i>Protaphane InnoLet (NI)</i> .....	63
<i>Predsol(QA)</i> .....	57	<i>Protaphane Penfill 3 mL(NO)</i> .....	63
<i>Predsolone(LN)</i> .....	229	PROTEIN FORMULA WITH AMINO ACIDS,	
<i>Predstone(LN)</i> .....	230	CARBOHYDRATES, VITAMINS AND MINERALS	
PREGABALIN .....	652	WITHOUT PHENYLALANINE, AND SUPPLEMENTED	
<i>Pregabalin AMNEAL(EA)</i> .....	652, 653	WITH DOCOSAHEXAENOIC ACID .....	824
<i>Pregabalin APOTEX (GX)</i> .....	652, 653	PROTEIN FORMULA WITH ARGININE, VITAMIN C AND	
<i>Pregabalin GH (GQ)</i> .....	652, 653	E .....	1673
<i>Pregabalin Sandoz(SZ)</i> .....	652, 653	PROTEIN FORMULA WITH ARGININE, VITAMIN C, E	
PREGABALIN-DRLA(RZ) .....	652, 653	AND ZINC .....	1673
<i>Pregabalin-Teva (TB)</i> .....	652, 653	PROTEIN FORMULA WITH CARBOHYDRATE, FAT,	
<i>Pregnyl(MK)</i> .....	219, 1628	VITAMINS AND MINERALS .....	788
<i>Prenoxad(PL)</i> .....	784	PROTEIN HYDROLYSATE FORMULA WITH MEDIUM	
PREPARED COAL TAR .....	192	CHAIN TRIGLYCERIDES .....	799, 801
<i>Presolol 100(AF)</i> .....	128	<i>Provera(PF)</i>	
<i>Presolol 200(AF)</i> .....	128	.ANTINEOPLASTIC AND IMMUNOMODULATING	
PREXUM 10 (RW) .....	134	AGENTS .....	343, 344
PREXUM 2.5 (RW) .....	133	.GENITO URINARY SYSTEM AND SEX HORMONES	
PREXUM 5 (RW) .....	134	.....	216
<i>Prexum Combi 5/1.25(RW)</i> .....	138	<i>Proxen SR 1000(IY)</i> .....	615, 616, 833
PREXUM Combi LD 2.5/0.625(RW) .....	138	<i>Proxen SR 750(IY)</i> .....	615, 616, 833
<i>Prezcobix(JC)</i> .....	1331	<i>Prozac 20(LY)</i> .....	706
<i>Prezista(JC)</i> .....	1320, 1321	<i>Prozac Tab(LY)</i> .....	706
PRIMIDONE .....	656	<i>ProZero(VF)</i> .....	824
<i>Primolut N(BN)</i> .....	216	PRYZEX ODT(RW) .....	683, 684
<i>Primoteston Depot(BN)</i> .....	213	PRYZEX(RW) .....	681, 682, 683
<i>Prioten 15(DO)</i> .....	79	PSEUDOEPHEDRINE .....	1671
<i>Prioten 30 (DO)</i> .....	79	PSYLLIUM HUSK POWDER .....	1645
<i>Prioten 45(DO)</i> .....	79	PTU(PL) .....	231
<i>Pristiq(PF)</i> .....	709	<i>Pulmicort Respules(AP)</i> .....	744
<i>Pritor Plus 40/12.5 mg(FI)</i> .....	148	<i>Pulmicort Turbuhaler(AP)</i> .....	743
<i>Pritor Plus 80/12.5 mg(FI)</i> .....	149	<i>Pulmozyme(RO)</i> .....	1071, 1310
<i>Pritor Plus 80/25 mg(FI)</i> .....	149	<i>Puregon 300 IU/0.36 mL(MK)</i> .....	219, 1628
<i>Pritor/Amlodipine(FI)</i> .....	151	<i>Puregon 600 IU/0.72 mL(MK)</i> .....	219, 1628
<i>Pro-Banthine(RW)</i> .....	222	<i>Puregon 900 IU/1.08 mL(MK)</i> .....	218, 1628
PROBENECID .....	620	<i>Purinethol(AS)</i> .....	287
<i>Probitor (SZ)</i> .....	38, 39	<i>PVA Tears(PE)</i> .....	780, 781
PROCAINE PENICILLIN .....	23, 241	<i>Pyralin EN(FZ)</i> .....	60, 61
<i>ProCalm (RW)</i> .....	49, 50	PYRANTEL .....	735
PROCHLORPERAZINE .....	25, 49	PYRIDOSTIGMINE .....	727
<i>Prochlorperazine AN(EA)</i> .....	49, 50	PYRIMETHAMINE .....	733
<i>Prochlorperazine GH (GQ)</i> .....	49, 50	<i>Qpril 10(AF)</i> .....	135
<i>Pro-Cid(PL)</i> .....	620	<i>Qpril 20 (AF)</i> .....	135
<i>Procur 100 (ED)</i>		<i>Qpril 5(AF)</i> .....	135
.ANTINEOPLASTIC AND IMMUNOMODULATING		QUEPINE XR(RW) .....	686
AGENTS .....	349	<i>Questran Lite(QA)</i> .....	167
.GENITO URINARY SYSTEM AND SEX HORMONES		<i>Quetia 100 (RW)</i> .....	686
.....	220	<i>Quetia 200 (RW)</i> .....	687
<i>Prodeine Forte (AV)</i> .....	645, 646	<i>Quetia 25 (RW)</i> .....	688
<i>Profore 66050016(SN)</i> .....	1674	<i>Quetia 300 (RW)</i> .....	687
<i>Profore Lite 66050415(SN)</i> .....	1674	QUETIAPINE .....	685, 687
PROGESTERONE .....	1626	<i>Quetiapine Actavis 100(ED)</i> .....	686
<i>Progout 100 (AF)</i> .....	620	<i>Quetiapine Actavis 200(ED)</i> .....	687
<i>Progout 100(AF)</i> .....	620	<i>Quetiapine Actavis 300(ED)</i> .....	687
<i>Progout 300 (AF)</i> .....	619	<i>Quetiapine AN (EA)</i> .....	686, 687
<i>Prograf XL (LL)</i> .....	607, 1039, 1277	<i>Quetiapine AN(EA)</i> .....	688
<i>Prograf(LL)</i> .....	607, 1039, 1278	<i>Quetiapine GH 100 (GQ)</i> .....	686
<i>Progynova(BN)</i> .....	214	<i>Quetiapine GH 200 (GQ)</i> .....	687
<i>Proladone(PL)</i> .....	638, 639	<i>Quetiapine GH 25(GQ)</i> .....	688
<i>Prolia(AN)</i> .....	630	<i>Quetiapine GH 300 (GQ)</i> .....	687
PROMETHAZINE		<i>Quetiapine RBX (RA)</i> .....	688
.ALIMENTARY TRACT AND METABOLISM .....	50	<i>Quetiapine RBX(RA)</i> .....	686, 687
.Prescriber Bag .....	26	<i>Quetiapine Sandoz (SZ)</i> .....	686, 687
.RESPIRATORY SYSTEM .....	749	<i>Quetiapine Sandoz(SZ)</i> .....	688
<i>Prontosan Wound Irrigation Solution(BR)</i> .....	1678	QUETIAPINE-AS XR (RW) .....	686, 687
PROPANTHELINE .....	222	<i>Quetiapine-DRLA (RZ)</i> .....	688
PROPRANOLOL .....	123	<i>Quetiapine-DRLA(RZ)</i> .....	686, 687

Quilonum SR(AS) .....	710	Redipred(AS).....	229
QUINAGOLIDE .....	209	Reedos 100 (DO) .....	666
QUINAPRIL .....	135	Reedos 200 (DO) .....	665
QUINAPRIL + HYDROCHLOROTHIAZIDE .....	139	Reedos 25(DO) .....	665
Quinapril generichealth(GQ) .....	135	Reedos 50(DO) .....	665
Quinate(RW).....	733	Refresh Liquigel(AG) .....	774, 775
QUININE.....	733	Refresh Night Time(AG) .....	778, 779
QuitX(AF).....	1669	Refresh Tears Plus(AG) .....	774, 775
QV Bath Oil(EO) .....	1653	Relistor(LM).....	831
Qvar 100 Autohaler(IA) .....	743	Relpax(PF).....	653
Qvar 100(IA) .....	743	Remeron SolTab (AF) .....	711, 712
Qvar 50 Autohaler(IA).....	743	Remicade (JC) ....	971, 975, 979, 984, 989, 994, 998, 1003, 1010, 1210, 1213, 1218, 1223, 1227, 1231, 1237, 1241, 1248
Qvar 50(IA).....	743	Remicade(JC) .....	1662
RABEPRAZOLE .....	40, 41	Reminyl(JC).....	721, 722, 723
Rabeprazole AN (EA) .....	41	Renagel(GZ).....	785, 1077, 1317
Rabeprazole AN(EA) .....	40, 41	Renastart(VF).....	826
Rabeprazole generichealth (GQ) .....	41	RenaStart(VF) .....	826
Rabeprazole generichealth(GQ) .....	40, 41	Renflexis(MK).....	971, 975, 979, 984, 989, 994, 998, 1003, 1010, 1210, 1213, 1218, 1223, 1227, 1231, 1237, 1241, 1248
Rabeprazole Sandoz (SZ) .....	40, 41	Renitec 20(MK) .....	132
Rabeprazole Sandoz(SZ) .....	41	Renitec Plus 20/6(MK).....	137
Rabeprazole SUN(RN) .....	40, 41	Renitec(MK) .....	132
Rabeprazole-DRLA (RZ).....	40, 41	ReoPro(JC) .....	97
Rabeprazole-DRLA(RZ).....	41	Repalyte New Formulation (SW) .....	56
Ralovera(FZ).....	216	Repalyte New Formulation(SW) .....	56
RALOXIFENE .....	630	Repatha(AN) .....	168, 170
Raloxifene AMNEAL(ED).....	630	Replicare Ultra 66000434(SN) .....	1688
Raloxifene AN (EA).....	630	Resolve Thrush(EO).....	1651
RALTEGRAVIR .....	1336	Resonium-A(SW).....	1673
Ramace 1.25 mg(AV) .....	136	Respikast 4 (RW) .....	748
Ramace 10 mg(AV) .....	135	Respikast 5 (RW) .....	749
Ramace 2.5 mg(AV) .....	136	Resprim Forte(AF).....	253
Ramace 5 mg(AV) .....	136	restore O.R.S. (EA) .....	56
RAMIPRIL.....	135, 136	restore O.R.S.(EA) .....	56, 1646
RAMIPRIL + FELODIPINE .....	140	RETEPLASE .....	102
Ramipril AN (EA) .....	135, 136	Retrovir(VI).....	1328
Ramipril AN(EA) .....	135	Revatio (PF) .....	899, 1136
Ramipril generichealth(GQ) .....	135, 136, 137	ReVia(BQ).....	731
Ramipril Sandoz (SZ) .....	135, 136	Revlimid(CJ).....	1040, 1041, 1042, 1044, 1279, 1281, 1282
Ramipril Sandoz(SZ) .....	136, 137	Revolade(NV).....	846, 1083
Ramipril Winthrop (WA) .....	136, 137	Rexulti(LU).....	690
Ramipril Winthrop(WA).....	135, 136	Reyataz(BQ).....	1319, 1320
Rancef (RA).....	246, 247	RHAMNUS FRANGULA + STERCULIA.....	52, 830, 1645
Rancef(RA) .....	246, 247	Riamet 20mg/120mg Dispersible(SZ).....	733
Rani 2 (AF).....	34	Riamet(SZ) .....	734
RANIBIZUMAB .....	766, 767, 769	RIBAVIRIN .....	276, 912, 913, 1150
RANITIDINE .....	34	Ridaura(BZ).....	618
Ranitidine AN(EA).....	35	Ridaura(GH) .....	618
Ranitidine GH (GQ) .....	35	RIFABUTIN .....	912, 1149
Ranitidine GH(GQ) .....	34	Rifadin(SW) .....	272
Ranitidine Sandoz (SZ).....	34	RIFAMPICIN.....	272
Ranitidine Sandoz(SZ).....	35	RIFAXIMIN .....	55
Ranmoxy (RA) .....	237, 238	RILPIVIRINE .....	1330
Ranmoxy(RA) .....	238	Rilutek(SW) .....	732
Ransim (RA) .....	164, 165, 166	RILUZOLE.....	732
Ranzepam(RA) .....	697, 698, 840	Riluzole Sandoz (SZ).....	732
Rapamune(PF) .....	367, 947, 948, 1186	Rimycin 150(AF).....	272
Rapilysin 10 U(GN).....	102	Rimycin 300(AF).....	272
RASAGILINE .....	676	RIOCIGUAT .....	883, 887, 1120, 1124
Razit 10 (DO).....	41	Risedro once a week (RW).....	1663
Razit 20 (DO).....	40, 41	Risedro once a week(RW).....	623
RBX Topiramate(RA).....	668, 669	RISEDRONATE .....	622, 1663
RCF(AB).....	824	RISEDRONATE (&) CALCIUM CARBONATE .....	627, 1664
Reandron 1000(BN).....	214	RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL .....	627, 1665
Reaptan 10/10 (RW).....	139	Risedronate AN(EA).....	623, 1663
Reaptan 10/5 (RW).....	140	Risedronate Sandoz (SZ).....	623
Reaptan 5/10 (RW).....	140		
Reaptan 5/5 (RW).....	140		
Rebif 44(SG).....	355		
REBOXETINE.....	712		
ReddyMax Plus D-Cal (RZ) .....	627		

<i>Risedronate Sandoz(SZ)</i> .....	1663	<i>Roxar 300 (RW)</i> .....	256
<i>Risedronate-GA (GN)</i> .....	1663	<i>Roxet 20(DO)</i> .....	707
<i>Rispa (RW)</i> .....	694, 696	<i>Roximycin(AF)</i> .....	256, 257
<i>Rispa(RW)</i> .....	692, 693, 695	<i>Roxin(RW)</i> .....	262
<i>Risperdal (JC)</i> .....	692, 693, 694, 695, 696	ROXITHROMYCIN .....	256
<i>Risperdal Consta(JC)</i> .....	693	<i>Roxithromycin AN (EA)</i> .....	256, 257
<i>Risperdal(JC)</i> .....	691, 695	<i>Roxithromycin GH (GQ)</i> .....	256, 257
<i>Rispericor 0.5(CR)</i> .....	694, 696	<i>Roxithromycin Sandoz(SZ)</i> .....	256, 257
<i>Rispericor 1(CR)</i> .....	692, 695	<i>Roxithromycin-GA(ED)</i> .....	256, 257
<i>Rispericor 2(CR)</i> .....	692, 693	<i>Rulide D(SW)</i> .....	256
RISPERIDONE .....	691, 692, 693, 694, 695	<i>Rulide(SW)</i> .....	256, 257
<i>Risperidone AMNEAL (EF)</i> .....	692, 693, 694, 695, 696	RUXOLITINIB .....	330, 331
<i>Risperidone AMNEAL(EF)</i> .....	692	<i>Rynacrom(SW)</i> .....	1670
<i>Risperidone generichealth (GQ)</i> .....	692	<i>Rythmodan(SW)</i> .....	113
<i>Risperidone generichealth(GQ)</i> .....	692, 693, 695	S-26 LF(AS) .....	809
<i>Risperidone Sandoz (SZ)</i> .....	692, 693, 695	S-26 Original LI(AS) .....	809
<i>Risperidone Sandoz(SZ)</i> .....	692, 694, 696	<i>Sabril(SW)</i> .....	661
<i>Rispernia (ER)</i> .....	692, 694, 696	SACUBITRIL + VALSARTAN .....	152
<i>Rispermia(ER)</i> .....	692, 693, 695	<i>Saflutan(MF)</i> .....	762
<i>Ristempa (GV)</i> .....	929, 1167	<i>Saizen(SG)</i> .....	1372, 1484, 1578
<i>Ritalin 10 (NV)</i> .....	717	<i>Salazopyrin(PF)</i> .....	60
<i>Ritalin LA(NV)</i> .....	717	<i>Salazopyrin-EN(PF)</i> .....	60, 61
<i>Rithmik 200(RW)</i> .....	114	SALBUTAMOL .....	
RITONAVIR .....	1322	. Prescriber Bag .....	26
RITUXIMAB .....		. RESPIRATORY SYSTEM .....	737, 747
. ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Salbutamol Actavis(EA)</i> .....	26, 737
. AGENTS .....	288, 289	<i>Salbutamol AN (JU)</i> .....	26, 737
. Highly Specialised Drugs Program (Private Hospital)920,		<i>Salbutamol Sandoz(SZ)</i> .....	26, 737
1045		SALCATONIN .....	233
. Highly Specialised Drugs Program (Public Hospital)1157,		SALICYLIC ACID + BENZALKONIUM CHLORIDE +	
1284		. ALCOHOL + COAL TAR SOLUTION +	
RIVAROXABAN .....	107, 108, 109	. POLYOXYETHYLENE ETHERS .....	1655
<i>Rivastigmelon Patch 10 (AF)</i> .....	724, 725	SALICYLIC ACID + LACTIC ACID .....	1656
<i>Rivastigmelon Patch 5 (AF)</i> .....	723, 724	SALMETEROL .....	738
RIVASTIGMINE .....	723, 724	<i>Salofalk(OA)</i> .....	58, 59, 60
<i>Rivotril(RO)</i> .....	23, 657, 658, 840	<i>SalplusF Inhaler 125/25 (YC)</i> .....	740
<i>Rixadone (AF)</i> .....	692, 693, 695	<i>SalplusF Inhaler 250/25 (YC)</i> .....	741
<i>Rixadone(AF)</i> .....	692, 694, 696	<i>Salpraz (AF)</i> .....	39, 40
RIZATRIPTAN .....	654	<i>Sandimmun(NV)</i> .....	1037, 1276
<i>Rizatriptan AN ODT (EA)</i> .....	654	<i>Sandomigran 0.5(AE)</i> .....	656
<i>Rizatriptan ODT GH(GQ)</i> .....	654	<i>Sandostatin 0.05 (NV)</i> .....	909, 1147
<i>Rizatriptan Wafers-10mg (AF)</i> .....	654	<i>Sandostatin 0.1 (NV)</i> .....	910, 1147
<i>Roaccutane (RO)</i> .....	206	<i>Sandostatin 0.5 (NV)</i> .....	909, 1147
<i>Rocaltrol(RO)</i> .....		<i>Sandostatin LAR(NV)</i> .....	908, 909, 1146
. ALIMENTARY TRACT AND METABOLISM .....	90	<i>Sandoz Lamotrigine (HX)</i> .....	665
. MUSCULO-SKELETAL SYSTEM .....	629	<i>Sandoz Nail Repair(SZ)</i> .....	1651
<i>Rocta 10(RW)</i> .....	206	<i>Sandoz Venlafaxine XR(HX)</i> .....	712, 713
<i>Rocta 20(RW)</i> .....	206	<i>Sandrena(AS)</i> .....	215
<i>Roferon-A(RO)</i> .....	353, 354, 929, 1167, 1337	<i>Saphris(LU)</i> .....	680, 681
ROMIPLOSTIM .....	846, 1083	SAPROPTERIN .....	92, 93
ROSIGLITAZONE + METFORMIN .....	73	SAQUINAVIR .....	1322
<i>Rostor 10(DO)</i> .....	160, 163	<i>Savacol Mouth and Throat Rinse(OM)</i> .....	1643
<i>Rostor 20(DO)</i> .....	160, 162	SAXAGLIPTIN .....	81
<i>Rostor 40(DO)</i> .....	160, 163	SAXAGLIPTIN + METFORMIN .....	74
<i>Rostor 5(DO)</i> .....	160, 163	<i>Sculptra(GA)</i> .....	787
ROSUVASTATIN .....	158, 159, 161, 162	<i>Scytera(RZ)</i> .....	192
ROSUVASTATIN (&) EZETIMIBE .....	183, 185	<i>Sebifin 250 (RA)</i> .....	192
<i>Rosuvastatin AMNEAL (EF)</i> .....	160, 162, 163	<i>SebiRinse(EO)</i> .....	1657
<i>Rosuvastatin AMNEAL(EF)</i> .....	158, 159, 161, 162	<i>Sebitar(EO)</i> .....	1655
<i>Rosuvastatin generichealth (HQ)</i> .....	160, 161, 162, 163	<i>Sebizole(EA)</i> .....	1651
<i>Rosuvastatin generichealth(HQ)</i> .....	158, 159, 161, 162	SECUKINUMAB ....	554, 556, 558, 559, 562, 565, 568, 571, 574
<i>Rosuvastatin GH (GQ)</i> .....	158, 159, 161, 162	<i>seebri breezhaler(NV)</i> .....	745
<i>Rosuvastatin GH(GQ)</i> .....	160, 161, 162, 163	SELEGILINE .....	677
<i>Rosuvastatin RBX (RA)</i> .....	160, 161, 162, 163	SELENIUM SULFIDE .....	1656
<i>Rosuvastatin Sandoz(SZ)</i> .....	160, 161, 162, 163	<i>Selsun(DQ)</i> .....	1656
<i>Rosuvastatin-DRLA (RI)</i> .....	158, 159, 161, 162	<i>Senna-Gen(PP)</i> .....	1644
<i>Rosuvastatin-DRLA(RI)</i> .....	160, 161, 162, 163	SENNOSIDE B .....	1644
<i>Rosuzet Composite Pack(MK)</i> .....	185, 188	<i>Senokot(RC)</i> .....	1645
ROTIGOTINE .....	676	<i>Seprtin Forte(RW)</i> .....	253
<i>Roxar 150 (RW)</i> .....	257		

<i>Septrin</i> (RW).....	253	<i>Simvar 10</i> (RW).....	164, 165
<i>Serenace</i> (QA).....	23, 678	<i>Simvar 20</i> (RW).....	164, 166
<i>Serepax</i> (QA).....	698, 699, 840	<i>Simvar 40</i> (RW).....	165, 166
<i>Seretide Accuhaler 100/50</i> (GK).....	740	<i>Simvar 80</i> (RW).....	164, 165
<i>Seretide Accuhaler 250/50</i> (GK).....	740	SIMVASTATIN.....	163, 165
<i>Seretide Accuhaler 500/50</i> (GK).....	741	<i>Simvastatin AN</i> (EA).....	164, 165, 166
<i>Seretide MDI 125/25</i> (GK).....	740	<i>Simvastatin generichealth</i> (GQ).....	164, 165, 166
<i>Seretide MDI 250/25</i> (GK).....	741	<i>Simvastatin Sandoz</i> (SZ).....	164, 165, 166
<i>Seretide MDI 50/25</i> (GK).....	740	<i>Simvastatin Sandoz</i> (SZ).....	164, 165
<i>Serevent Accuhaler</i> (GK).....	738	<i>Simvastatin-GA 10</i> (ED).....	164, 165
<i>Seroquel</i> (AP).....	688	<i>Simvastatin-GA 20</i> (ED).....	164, 166
<i>Seroquel XR</i> (AP).....	686	<i>Simvastatin-GA 40</i> (ED).....	165, 166
<i>Seroquel XR</i> (AP).....	686, 687	<i>Simvastatin-GA 80</i> (ED).....	164, 165
<i>Seroquel</i> (AP).....	686, 687	<i>Sinemet 100/25</i> (MK).....	672
<i>Sertra 100</i> (RW).....	707	<i>Sinemet CR</i> (MK).....	672
<i>Sertra 50</i> (RW).....	707	<i>Sinemet</i> (MK).....	672
<i>Sertracor 100</i> (CR).....	707	<i>Sinequan</i> (PF).....	702
<i>Sertracor 50</i> (CR).....	707	<i>Singulair</i> (MK).....	748, 749
SERTRALINE.....	707	<i>Sintetica Baclofen Intrathecal</i> (BZ).....	1050, 1051, 1289
<i>Sertraline AN</i> (EA).....	707, 708	SIROLIMUS.....	367, 947, 1186
<i>Sertraline generichealth</i> (GQ).....	707	SITAGLIPTIN.....	82
<i>Sertraline Sandoz</i> (SZ).....	707	SITAGLIPTIN + METFORMIN.....	75
<i>Setopress 3505</i> (MH).....	1674	SKIN EMOLLIENT.....	1653
<i>Setrona</i> (RA).....	707	<i>Slow-K</i> (NV).....	91
SEVELAMER.....	784, 1077, 1316	<i>Sno-Pro</i> (SB).....	824
<i>Sevikar 20/5</i> (MK).....	150	<i>Sodibic</i> (AS).....	222
<i>Sevikar 40/10</i> (MK).....	151	SODIUM AUROTHIOMALATE.....	618
<i>Sevikar 40/5</i> (MK).....	151	SODIUM CHLORIDE.....	1650
<i>Sevikar HCT 20/5/12.5</i> (MK).....	152	SODIUM CHLORIDE + HYPOCHLOROUS ACID + SODIUM HYPOCHLORITE.....	1694
<i>Sevikar HCT 40/10/12.5</i> (MK).....	152	SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID.....	55, 56, 1646
<i>Sevikar HCT 40/10/25</i> (MK).....	152	SODIUM HYALURONATE.....	781
<i>Sevikar HCT 40/5/12.5</i> (MK).....	152	SODIUM POLYSTYRENE SULFONATE.....	1673
<i>Sevredol</i> (MF).....	635, 834	<i>Sodium Valproate Sandoz</i> (SZ).....	661
<i>Shilova 500</i> (DO).....	277	<i>Soflax</i> (EA).....	1644
<i>Sical</i> (AF).....		SOFOSBUVIR.....	281, 282, 917, 1154, 1155
.ALIMENTARY TRACT AND METABOLISM.....	90	SOFOSBUVIR + VELPATASVIR.....	282, 917, 1155
.MUSCULO-SKELETAL SYSTEM.....	629	<i>Sofradex</i> (SW).....	782
<i>Sifrol</i> (BY).....	674	<i>Soframycin</i> (SW).....	783
<i>Sifrol ER</i> (BY).....	675	<i>Solaraze 3% Gel</i> (FK).....	1656
<i>Sifrol</i> (BY).....	676	<i>Solavert</i> (RF).....	115
<i>Sigmacort</i> (QA).....	194	<i>Solian 100</i> (SW).....	689
<i>Sigmaxin</i> (FM).....	113	<i>Solian 200</i> (SW).....	688
<i>Sigmaxin-PG</i> (FM).....	113	<i>Solian 400</i> (SW).....	688
<i>Signifor LAR</i> (NV).....	911, 1149	<i>Solian Solution</i> (SW).....	688
<i>Silaran</i> (RA).....	1659	<i>Soliris</i> (XI).....	938, 939, 941, 945, 1176, 1178, 1179, 1183
SILDENAFIL.....		<i>Solone</i> (IA).....	229
.Highly Specialised Drugs Program (Private Hospital).....	894	<i>SoloSite Gel 36361338</i> (SN).....	1691
.Highly Specialised Drugs Program (Public Hospital).....	1132	<i>Solprin</i> (RC).....	
.Repatriation Pharmaceutical Benefits Scheme.....	1658	.BLOOD AND BLOOD FORMING ORGANS.....	98
<i>Sildenafil Actavis</i> (EA).....	1659	.NERVOUS SYSTEM.....	650
<i>Sildenafil Actavis</i> (EA).....	1658, 1659	<i>Solu-Cortef</i> (PF).....	24, 228
<i>Sildenafil AN PHT 20</i> (EA).....	899, 1137	<i>Solugel 10336</i> (JJ).....	1690
<i>Sildenafil generichealth</i> (GQ).....	1659	<i>Solu-Medrol</i> (PF).....	228, 229
<i>Sildenafil Sandoz PHT 20</i> (SZ).....	899, 1137	<i>Somac</i> (NQ).....	39, 40
SILDENAFIL-DRx (RZ).....	899, 1137	SOMATROPIN 1349, 1357, 1364, 1372, 1381, 1389, 1399, 1414, 1431, 1448, 1466, 1484, 1502, 1521, 1540, 1559, 1578, 1601	
<i>Silic 15</i> (EO).....	1652	<i>Somatuline Autogel</i> (IS).....	908, 1145
SILVER SULFADIAZINE.....	194	<i>Somatuline LA</i> (IS).....	907, 1145
<i>Simbrinza 1%/0.2%</i> (NV).....	757	<i>Somavert</i> (PF).....	905, 907, 1142, 1144
<i>Simipex 0.125</i> (RW).....	674	<i>Sone</i> (IA).....	229
<i>Simipex 0.25</i> (RW).....	674	SORAFENIB.....	332, 333
<i>Simipex 1</i> (RW).....	674	<i>Sorbact Absorption Dressing S98222</i> (QL).....	1690
<i>SIMIPEX XR</i> (RW).....	675	<i>Sorbact Foam Dressing S98310</i> (QL).....	1691
<i>Simplotan</i> (FZ).....	264	<i>Sorbact Ribbon Gauze S98118</i> (QL).....	1691
<i>Simponi</i> (JC).....	528, 532, 534, 537, 539, 543	<i>Sorbact Ribbon Gauze S98120</i> (QL).....	1691
<i>Simpral</i> (AF).....	674		
<i>Simvacor 10</i> (CR).....	164, 165		
<i>Simvacor 20</i> (CR).....	164, 166		
<i>Simvacor 40</i> (CR).....	165, 166		
<i>Simvacor 80</i> (CR).....	164, 165		

SORBITOL + CITRIC ACID + LAURYL SULFOACETATE	
SODIUM.....	54, 831, 1645
Sorbsan 1410(UM) .....	1680
Sorbsan 1411(UM) .....	1679
Sotacor(RW).....	115
SOTALOL.....	114
Sotalol Sandoz (SZ).....	115
Sovaldi(GI).....	282, 917, 1155
SOY LECITHIN + TOCOPHEROL + VITAMIN A.....	781
SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE .....	824
Sozol (RW) .....	39, 40
Span-K(AS).....	91
Spiolto Respimat(BY) .....	742
Spiractin 100(AF).....	122
Spiractin 25(AF).....	122
Spiriva Respimat(BY) .....	745, 746
Spiriva(BY).....	745
SPIRONOLACTONE .....	122
Sporanox (JC).....	268
Spren 100(OW).....	98, 1648
Sprycel(BQ) .....	297, 298, 299, 301
Stalevo 100/25/200mg(NV).....	673
Stalevo 125/31.25/200mg(NV).....	672
Stalevo 150/37.5/200mg(NV).....	673
Stalevo 200/50/200mg(NV).....	673
Stalevo 50/12.5/200mg(NV).....	673
Stalevo 75/18.75/200mg(NV).....	673
Staphylex 250(AF) .....	242
Staphylex 500(AF).....	242, 243
STAVUDINE .....	1326
Stelara(JC).....	588, 591, 595, 600, 606, 1037, 1276
Stelax 10(RW) .....	619
Stelax 25(RW) .....	619
Stelazine(GH).....	678
Stemetil(SW).....	25, 49, 50
Stemzine(AV).....	49, 50
Steripaste 3610(MH).....	1678
Stocrin(MK).....	1328, 1329
Strattera(LY).....	714, 715
Stribild(GI).....	1334
Stromectol(MK).....	735
Suboxone Film 2/0.5(IR) .....	1632
Suboxone Film 8/2(IR).....	1632
Subutex(IR).....	1632
SUCCINYLATED GELATIN.....	112
SUCRALFATE .....	42
SUCROFERRIC OXYHYDROXIDE.....	785, 1077, 1317
SULFASALAZINE.....	60
Sulprix (AF).....	688
Sulprix(AF).....	688, 689
SULTHIAME .....	668
Sumatran (OW).....	655
Sumatran(OW).....	655
SUMATRIPTAN .....	654
Sumatriptan AN (EA) .....	655
Sumatriptan generichealth(GQ) .....	655
Sumatriptan RBX (RA).....	655
Sumatriptan Sandoz(SZ) .....	655
SUNITINIB.....	333, 334, 335
SUNSCREENS.....	1653
Sunsense Sensitive SPF 50+(EO).....	1653
Sunsense Ultra SPF 50+(EO).....	1653
Surepress 650947(CC).....	1674
Surepress 650948(CC).....	1674
Sutent(PF) .....	333, 334, 335, 336
Symbicort Rapihaler 100/3(AP) .....	738
Symbicort Rapihaler 200/6(AP) .....	739
Symbicort Rapihaler 50/3(AP) .....	739
Symbicort Turbuhaler 100/6(AP) .....	738
Symbicort Turbuhaler 200/6(AP) .....	738
Symbicort Turbuhaler 400/12(AP) .....	739
Symmetrel 100(NV).....	673
Synacthen Depot 1 mg/1 mL(LM).....	224
Synarel(PF) .....	226, 1629
Syquet (AF) .....	686, 687
Syquet(AF) .....	688
Systane(NV).....	779, 780
Tacidine (AF).....	34
TACROLIMUS.....	607, 1038, 1277
TACROLIMUS APOTEX (TX) .....	607, 1039, 1278
Tacrolimus Sandoz(SZ).....	607, 1039, 1277, 1278
TADALAFIL .....	
Highly Specialised Drugs Program (Private Hospital).....	899
Highly Specialised Drugs Program (Public Hospital).....	1137
Repatriation Pharmaceutical Benefits Scheme .....	1659
Tafinlar(NV) .....	295, 296
TAFLUPROST.....	762
Talam (RW) .....	703
Talam(RW).....	703
Taltz(LY).....	549, 554
Tamate (AF) .....	668, 669
Tambocor (IA) .....	114
Tambocor(IA) .....	114
Tamosin(QA) .....	348
TAMOXIFEN .....	347, 348
Tamoxifen Sandoz (SZ).....	348
Tamsil(RW) .....	192, 1652
TAMSULOSIN .....	1660
Tamsulosin Sandoz SR (SZ) .....	1660
TAPE NON WOVEN RETENTION POLYACRYLATE.....	1694
TAPE PLASTER ADHESIVE ELASTIC.....	1694
TAPE PLASTER ADHESIVE HYPOALLERGENIC .....	1694
TAPE PLASTER ADHESIVE WITH SILICONE.....	1695
TAPENTADOL .....	646
TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR .....	1656
Tarceva(RO).....	301, 302
Targin 10/5mg(MF).....	640
Targin 15/7.5mg(MF).....	641
Targin 2.5/1.25 mg(MF).....	641
Targin 20/10mg(MF).....	641
Targin 30/15 mg(MF).....	641
Targin 40/20mg(MF).....	641
Targin 5/2.5mg(MF).....	641
Targin 60/30(MF).....	641
Targin 80/40(MF).....	641
Tarka 2/180(GO) .....	140
Tarka 4/240(GO) .....	140
Tasigna(NV) .....	321, 323
Tazac(RW) .....	34
Tears Naturale(NV) .....	776
tearsagain(RB) .....	781, 782
Tecfidera(BD).....	731, 732
Tegaderm Transparent 1628(MM) .....	1681
Tegaderm Transparent Island 3582(MM) .....	1681
Tegaderm Transparent Island 3586(MM) .....	1681
Tegretol 100(NV).....	659
Tegretol 200(NV).....	659
Tegretol CR 200(NV).....	659
Tegretol CR 400(NV).....	658, 659
Tegretol Liquid(NV) .....	659
Telfa 8252F(KE) .....	1676
Telfa 8253F(KE) .....	1676
Telfa 8254F(KE) .....	1675
Telfast 120(SW) .....	1672
Telfast(SW) .....	1672
TELMISARTAN .....	144
TELMISARTAN + AMLODIPINE .....	151
TELMISARTAN + HYDROCHLOROTHIAZIDE.....	148

Telmisartan AN (EA)	144	Terry White Chemists Alendronate Plus D3 70 mg/140 mcg(TW)	625, 1664
Telmisartan GH (GQ)	144	Terry White Chemists Alendronate Plus D3 70 mg/70 mcg (TW)	626
Telmisartan HCT GH 40/12.5 (GQ)	148	Terry White Chemists Alendronate Plus D3 70 mg/70 mcg(TW)	1664
Telmisartan HCT GH 80/12.5 (GQ)	149	Terry White Chemists Allopurinol(TW)	620
Telmisartan HCT GH 80/25 (GQ)	149	Terry White Chemists Amitriptyline(TW)	701
Telmisartan HCTZ AN 40/12.5 (EA)	148	Terry White Chemists Amlodipine (TW)	128, 129
Telmisartan HCTZ AN 80/12.5 (EA)	149	Terry White Chemists Amoxicillin and Clavulanic Acid (TW)	243, 244
Telmisartan HCTZ AN 80/25 (EA)	149	Terry White Chemists Atenolol(TW)	124
Telmisartan Sandoz(SZ)	144	Terry White Chemists Atorvastatin (TW)	153, 154, 155
Telmisartan/HCT Sandoz(SZ)	148, 149	Terry White Chemists Azithromycin(TW)	1661
Telmisartan-DRLA(RZ)	144	Repatriation Pharmaceutical Benefits Scheme	1661
Teltartan (RW)	144	Terry White Chemists Azithromycin(TW)	254
Teltartan HCT 40/12.5(RW)	148	ANTIINFECTIVES FOR SYSTEMIC USE	254
Teltartan HCT 80/12.5(RW)	149	SENSORY ORGANS	750
Teltartan HCT 80/25(RW)	149	Terry White Chemists Bisoprolol(TW)	124, 125
Telzir(VI)	1321	Terry White Chemists Candesartan (TW)	142
Temaze (AF)	700, 701, 841	Terry White Chemists Candesartan HCTZ 16/12.5(TW)	145
TEMAZEPAM	700, 841	Terry White Chemists Candesartan HCTZ 32/12.5(TW)	145
Temizole 100(QA)	284, 286	Terry White Chemists Candesartan HCTZ 32/25(TW)	146
Temizole 140(QA)	284, 285	Terry White Chemists Candesartan(TW)	141
Temizole 20(QA)	284, 285	Terry White Chemists Carvedilol 12.5 mg(TW)	127
Temizole 250(QA)	285	Terry White Chemists Carvedilol 25 mg(TW)	127
Temizole 5(QA)	284, 285	Terry White Chemists Carvedilol 3.125 mg (TW)	128
Temodal (MK)	284, 285, 286	Terry White Chemists Carvedilol 6.25 mg(TW)	127
Temodal(MK)	284, 286	Terry White Chemists Celecoxib(TW)	617
Temolide (JU)	284, 286	Terry White Chemists Citalopram(TW)	703
Temolide(JU)	284, 285, 286	Terry White Chemists Clarithromycin(TW)	255
TEMOZOLOMIDE	284, 285	Terry White Chemists Clindamycin (TW)	257, 258
Temozolomide Alphapharm (AF)	284, 285, 286	Terry White Chemists Clopidogrel (TW)	99, 1649
Temozolomide Amneal(ED)	284, 285, 286	Terry White Chemists Clopidogrel(TW)	98
Temtabs(FM)	700, 701, 841	Terry White Chemists Clopidogrel/Aspirin 75/100 (TW)	100
Tenaxil SR(RW)	120	Terry White Chemists Donepezil(TW)	719, 720, 721
TenderWet 24 Active 609210(HR)	1685	Terry White Chemists Doxycycline (TW)	236
TenderWet 24 Active 609213(HR)	1686	Terry White Chemists Doxycycline(TW)	234, 235
TenderWet Active Cavity 609272(HR)	1685	Terry White Chemists Duloxetine(TW)	710
TENECTEPLASE	102	Terry White Chemists Escitalopram(TW)	704
TENOFOVIR	1326	Terry White Chemists Fluoxetine (TW)	706
TENOFOVIR + EMTRICITABINE	1333	Terry White Chemists Frusemide(TW)	121
TENOFOVIR + EMTRICITABINE + EFAVIRENZ	1334	Terry White Chemists Gliclazide MR (TW)	66
TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT	1334	Terry White Chemists Gliclazide(TW)	66
TENOFOVIR + EMTRICITABINE + RILPIVIRINE	1334	Terry White Chemists Hydroxychloroquine (TW)	618
TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT	1335	Terry White Chemists Indapamide SR (TW)	120
Tenofovir Disoproxil Emtricitabine Mylan 300/200(AF)	1334	Terry White Chemists Irbesartan (TW)	142, 143
Tenofovir Disoproxil Mylan(AF)	1328	Terry White Chemists Irbesartan HCTZ (TW)	147
Tenofovir EMT GH(GQ)	1334	Terry White Chemists Irbesartan HCTZ(TW)	147
Tenofovir GH(GQ)	1328	Terry White Chemists Irbesartan(TW)	143
Tenolten 50(DO)	124	Terry White Chemists Isosorbide Mononitrate (TW)	117
Tenormin(AP)	124	Terry White Chemists Latanoprost(TW)	761
Tensig (RW)	124	Terry White Chemists Lercanidipine(TW)	129, 130
Tensocrepe 36300501(BV)	1676	Terry White Chemists Letrozole (TW)	353
Tensocrepe 36301001(BV)	1675	Terry White Chemists Lisinopril (TW)	133
Tensocrepe 36307501(BV)	1676	Terry White Chemists Meloxicam (TW)	612, 613
Tensopress 71723-00(BV)	1674	Terry White Chemists Meloxicam 15 mg (TW)	612
TERBINAFINE		Terry White Chemists Meloxicam 7.5 mg (TW)	613
.DERMATOLOGICALS	191, 192	Terry White Chemists Metformin 1000 (TW)	64
Repatriation Pharmaceutical Benefits Scheme	1651, 1652	Terry White Chemists Metformin XR 1000 (TW)	65
Terbinafine AN (EA)	192	Terry White Chemists Metformin XR 500(TW)	65
Terbinafine GH (GQ)	192, 1652	Terry White Chemists Metformin(TW)	65
Terbinafine Sandoz(SZ)	192, 1652	Terry White Chemists Metoprolol (TW)	126
Terbinafine-DRLA(RZ)	192	Terry White Chemists Mirtazapine (TW)	711
TERBUTALINE		Terry White Chemists Montelukast(TW)	748, 749
.RESPIRATORY SYSTEM	738, 747	Terry White Chemists Olanzapine (TW)	681, 682, 683
TERIFLUNOMIDE	367	Terry White Chemists Omeprazole(TW)	38, 39
TERIPARATIDE		Terry White Chemists Paroxetine (TW)	707
.MUSCULO-SKELETAL SYSTEM	630	Terry White Chemists Perindopril (TW)	134, 135
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS	232	Terry White Chemists Perindopril(TW)	134

<i>Terry White Chemists Perindopril/ Indapamide 4/1.25 (TW)</i> .....	138	<i>Titralac(MM)</i> .....	1643
<i>Terry White Chemists Pioglitazone (TW)</i> .....	79	<i>Tivicay(VI)</i> .....	1335
<i>Terry White Chemists Pioglitazone(TW)</i> .....	79	<i>Tixol (AL)</i> .....	710
<i>Terry White Chemists Pravastatin (TW)</i> .....	156, 157, 158	<i>TOBI podhaler(NV)</i> .....	259
<i>Terry White Chemists Prazosin (TW)</i> .....	119	<i>Tobi(NV)</i> .....	259
<i>Terry White Chemists Quetiapine (TW)</i> .....	688	<i>Tobra-Day(PL)</i> .....	258
<i>Terry White Chemists Quetiapine(TW)</i> .....	686, 687	<b>TOBRAMYCIN</b>	
<i>Terry White Chemists Rabeprazole(TW)</i> .....	41	<b>ANTIINFECTIVES FOR SYSTEMIC USE</b> .....	258, 259
<i>Terry White Chemists Ramipril (TW)</i> .....	135, 136, 137	<b>SENSORY ORGANS</b> .....	750, 751
<i>Terry White Chemists Ramipril(TW)</i> .....	136, 137	<i>Tobramycin AN (EA)</i> .....	259
<i>Terry White Chemists Ranitidine (TW)</i> .....	35	<i>Tobramycin Mylan (AF)</i>	
<i>Terry White Chemists Ranitidine(TW)</i> .....	34	<b>ANTIINFECTIVES FOR SYSTEMIC USE</b> .....	258
<i>Terry White Chemists Rizatriptan (TW)</i> .....	654	<i>Tobrex(NV)</i> .....	751
<i>Terry White Chemists Rosuvastatin (TW)</i> .....	160, 161, 162, 163	<b>TOCILIZUMAB</b> ...	579, 581, 1010, 1017, 1024, 1029, 1249, 1255, 1262, 1267
<i>Terry White Chemists Rosuvastatin(TW)</i>	158, 159, 161, 162	<b>TOFACITINIB</b> .....	368, 370
<i>Terry White Chemists Roxithromycin (TW)</i> .....	256, 257	<i>Tofranil 10(GH)</i> .....	702
<i>Terry White Chemists Sertraline(TW)</i> .....	707	<i>Tofranil 25(GH)</i> .....	703
<i>Terry White Chemists Sildenafil(TW)</i> .....	1659	<b>TOLNAFTATE</b> .....	1651
<i>Terry White Chemists Simvastatin(TW)</i> .....	164, 165, 166	<i>Topamax Sprinkle(JC)</i> .....	669
<i>Terry White Chemists Sumatriptan (TW)</i> .....	655	<i>Topamax(JC)</i> .....	668, 669, 670
<i>Terry White Chemists Tramadol SR (TW)</i> .....	647, 648	<b>TOPIRAMATE</b> .....	668, 669
<i>Terry White Chemists Tramadol SR(TW)</i> .....	648	<i>Topiramate AN (EA)</i> .....	668, 669, 670
<i>Terry White Chemists Tramadol(TW)</i> .....	648, 649	<i>Topiramate GH(GQ)</i> .....	668, 669, 670
<i>Terry White Chemists Valaciclovir (TW)</i> .....	277	<i>Topiramate Sandoz (SZ)</i> .....	668, 669, 670
<i>Terry White Chemists Valaciclovir(TW)</i> .....	278	<i>Topra 40(DO)</i> .....	39, 40
<i>Terry White Chemists Venlafaxine XR (TW)</i> .....	712, 713	<i>Toprol-XL 190(AP)</i> .....	126
<i>Terry White Chemists Zopiclone (TW)</i> .....	1669	<i>Toprol-XL 23.75(AP)</i> .....	125
<i>Tertroxin(QA)</i> .....	231	<i>Toprol-XL 47.5(AP)</i> .....	125
<i>Testogel(HB)</i> .....	212	<i>Toprol-XL 95(AP)</i> .....	125
<b>TESTOSTERONE</b> .....	211	<b>TOREMIFENE</b> .....	348
<b>TESTOSTERONE ENANTHATE</b> .....	212	<i>Torvastat 10(RW)</i> .....	154, 155
<b>TESTOSTERONE UNDECANOATE</b> .....	213	<i>Torvastat 20(RW)</i> .....	154, 155
<b>TETRABENAZINE</b> .....	732	<i>Torvastat 40(RW)</i> .....	153, 155
<b>TETRACOSACTRIN</b> .....	224	<i>Torvastat 80(RW)</i> .....	154, 155
<i>TevaGrastim(TB)</i> .....	924, 1162	<i>Tracleer (AT)</i> .....	864, 1101
<i>Tevaripirazole(TB)</i> .....	689	<i>Tracleer(AT)</i> .....	869, 1107
<i>Tevatiapine XR (TB)</i> .....	686, 687	<i>Trajenta(BY)</i> .....	81
<i>Tevatiapine XR(TB)</i> .....	686	<i>Trajentamet(BY)</i> .....	72, 73
<i>Teveten Plus 600/12.5(GO)</i> .....	146	<b>TRAMADOL</b> .....	26, 647, 648, 649
<i>Teveten(GO)</i> .....	142	<i>Tramadol ACT(EA)</i> .....	26, 647, 649
<b>THALIDOMIDE</b> .....	1049, 1288	<i>Tramadol AMNEAL (EF)</i> .....	648, 649
<i>Thalomid(CJ)</i> .....	1049, 1050, 1288	<i>Tramadol AN SR (EA)</i> .....	648
<b>THEOPHYLLINE</b> .....	747	<i>Tramadol AN SR(EA)</i> .....	647, 648
<i>TheraTears(CX)</i> .....	774, 775	<i>Tramadol AN(EA)</i> .....	648, 649
<b>THIAMINE</b> .....	90, 1647	<i>Tramadol Sandoz (SZ)</i> .....	26, 647, 648, 649
<b>THIOGUANINE</b> .....	287	<i>Tramadol Sandoz SR (SZ)</i> .....	647, 648
<i>Thioprine 50 (AF)</i> .....	608	<i>Tramadol Sandoz SR(SZ)</i> .....	648
<i>Thyrogen(GZ)</i> .....	224	<i>Tramadol SCP(CR)</i> .....	648, 649
<b>THYROTROPIN ALFA</b> .....	224	<i>Tramadol SR generichealth (GQ)</i> .....	648
<b>THYROXINE</b> .....	231	<i>Tramadol SR generichealth(GQ)</i> .....	647, 648
<b>TIAGABINE</b> .....	660	<i>Tramal 100(CS)</i> .....	26, 647, 649
<b>TICAGRELOR</b> .....	101	<i>Tramal SR 100(CS)</i> .....	648
<b>TICARCILLIN + CLAVULANIC ACID</b> .....	245	<i>Tramal SR 150(CS)</i> .....	647
<i>Tielle MTL101E(KI)</i> .....	1686	<i>Tramal SR 200(CS)</i> .....	648
<i>Tielle MTL103(KI)</i> .....	1686	<i>Tramal SR 50(CS)</i> .....	648
<i>Tilade CFC-Free(SW)</i> .....	746	<i>Tramal(CS)</i> .....	647, 649
<i>Timentin(AS)</i> .....	245	<i>Tramedo (AF)</i> .....	648, 649
<b>TIMOLOL</b> .....	759	<i>Tramedo SR 100(AF)</i> .....	648
<i>Timoptol XE(MF)</i> .....	759	<i>Tramedo SR 150 (AF)</i> .....	647
<i>Timoptol(MF)</i> .....	759	<i>Tramedo SR 200 (AF)</i> .....	648
<i>Tinaderm(BN)</i> .....	1651	<b>TRAMETINIB</b> .....	336
<i>Tinasil (AF)</i> .....	192, 1652	<i>Tranalpha (AF)</i> .....	137
<b>TINIDAZOLE</b> .....	264	<i>Trandate(QA)</i> .....	128
<b>TIOTROPIUM</b> .....	745	<b>TRANDOLAPRIL</b> .....	137
<b>TIOTROPIUM + OLODATEROL</b> .....	742	<b>TRANDOLAPRIL + VERAPAMIL</b> .....	140
<b>TIPRANAVIR</b> .....	1322	<b>TRANEXAMIC ACID</b> .....	110
<b>TIROFIBAN</b> .....	101	<i>Transiderm-Nitro 25(SZ)</i> .....	116
<i>Tirofiban AC (JO)</i> .....	102	<i>Transiderm-Nitro 50(SZ)</i> .....	116
		<b>TRANLYCYPROMINE</b> .....	708

TRASTUZUMAB.....	290, 291, 292	TYR Anamix junior LQ(SB).....	811
Travatan(NV).....	762	TYR Anamix Junior(SB).....	816
TRAVOPROST.....	762	TYR cooler 10(VF).....	816
TRAVOPROST + TIMOLOL.....	762	TYR cooler 15(VF).....	815
TRIAMCINOLONE		TYR cooler 20(VF).....	815
DERMATOLOGICALS.....	194	TYR Easy Shake & Go(OH).....	811
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		TYR express 15(VF).....	815
HORMONES AND INSULINS.....	230	TYR express 20(VF).....	816
TRIAMCINOLONE + NEOMYCIN SULFATE +		TYR gel(VF).....	815
GRAMICIDIN + NYSTATIN.....	782	TYR Lophlex LQ 20(SB).....	815
Triasyn 2.5/2.5(SW).....	140	Tyrosine 1000(VF).....	825
Triasyn 5.0/5.0(SW).....	140	TYROSINE WITH CARBOHYDRATE.....	825
Tricortone(FM).....	194, 195	Tysabri(BD).....	947, 1186
Trifeme 28(FZ).....	210	Ulcacid(RA).....	35
TRIFLUOPERAZINE.....	678	ultibro breezhaler 110/50(NV).....	742
TRIGLYCERIDES LONG CHAIN.....	789	UMECLIDINIUM.....	746
TRIGLYCERIDES LONG CHAIN WITH GLUCOSE		UMECLIDINIUM + VILANTEROL.....	742
POLYMER.....	824	Uracol(EA).....	1660
TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN		Ural Sachets (QA).....	1660
WITH GLUCOSE POLYMER.....	824	UREA.....	1652
TRIGLYCERIDES MEDIUM CHAIN FORMULA		Urederm(KY).....	1652
VARIOUS.....	802, 803, 824	Uremide (AF).....	121
Trileptal(NV).....	660	Urex(RW).....	121
TRIMETHOPRIM.....	252, 253	Urex-Forte(RW).....	121
TRIMETHOPRIM + SULFAMETHOXAZOLE.....	253	Urex-M(RW).....	121
Triphasil 28(PF).....	210	Uro-Carb(YN).....	727
Tripriam(RW).....	252, 253	Uromitexan(BX).....	786
TRIPTORELIN.....	347, 1630	URSODEOXYCHOLIC ACID.....	50
Triquilar ED(BN).....	210	Ursodox GH (GQ).....	50
Tritace 1.25 mg (SW).....	136	Ursofalk(OA).....	50
Tritace 10 mg(SW).....	135	Ursosan (BZ).....	50
Tritace 2.5 mg (SW).....	136	USTEKINUMAB.....	585, 588, 591, 595, 600, 1034, 1272
Tritace 5 mg (SW).....	137	Utrogestan(HB).....	1626
Tritace(SW).....	136	Vaclovir (AF).....	278
Triumeq(VI).....	1332	Vaclovir(AF).....	277
Trizivir(VI).....	1331	Vagifem Low(NO).....	214
TROPISETRON.....	47	VALACICLOVIR.....	277, 278, 913, 1151
Tropisetron-AFT(AE).....	47	Valaciclovir AN (EA).....	277
Trovas (RA).....	153, 154, 155	Valaciclovir AN(EA).....	278
Trusamide(QA).....	758	Valaciclovir generichealth (GQ).....	278
Trusopt (MF).....	758	Valaciclovir generichealth(GQ).....	277
Truvada(GI).....	1334	Valaciclovir RBX (RA).....	277, 913, 1151
Tryzan Caps 1.25 (AF).....	136	Valaciclovir RBX(RA).....	278
Tryzan Caps 10 (AF).....	135	Valaciclovir Sandoz (SZ).....	278
Tryzan Caps 2.5(AF).....	136	Valaciclovir Sandoz(SZ).....	277
Tryzan Caps 5(AF).....	137	Valaciclovir SZ (HX).....	277
Tryzan Tabs 1.25(AF).....	136	Valaciclovir SZ(HX).....	277
Tryzan Tabs 10 (AF).....	136	Valacor 500 (CR).....	277
Tryzan Tabs 2.5(AF).....	136	Valacor 500(CR).....	277, 278
Tryzan Tabs 5(AF).....	137	Valcyte(RO).....	914, 1151, 1319
Tubegauz 0501633(SS).....	1676	VALGANCICLOVIR.....	913, 1151, 1319
Tubifast 2434(MH).....	1677	Valganciclovir AN (EA).....	914, 1151, 1319
Tubifast 2436(MH).....	1677	Valganciclovir Juno(JU).....	914, 1151, 1319
Tubifast 2438(MH).....	1677	Valganciclovir Mylan (AF).....	914, 1151, 1319
Tubigrip 1479(MH).....	1677	Valganciclovir Sandoz(SZ).....	914, 1151, 1319
Tubigrip 1480(MH).....	1677	Valine 1000(VF).....	825
Tubigrip 1481(MH).....	1677	Valine 50(VF).....	825
Tubigrip 1482(MH).....	1677	VALINE WITH CARBOHYDRATE.....	825
Tubigrip 1483(MH).....	1677	Valium(RO).....	697, 698, 840
Tubigrip 1484(MH).....	1677	Valpam 2 (RW).....	697, 840
Tubigrip 1486(MH).....	1677	Valpam 5 (RW).....	697, 698, 840
Tubigrip B 1520(MH).....	1676	Valprease 200 (RW).....	661
Tubigrip C 1545(MH).....	1676	Valprease 500 (RW).....	661
Tubigrip D 1546(MH).....	1676	Valpro 200(AF).....	661
Tubigrip E 1547(MH).....	1676	Valpro 500(AF).....	661
Tubigrip F 1548(MH).....	1676	VALPROATE.....	660
Twynsta(BY).....	151	Valproate Winthrop EC 200 (WA).....	661
Tykerb(NV).....	318	Valproate Winthrop EC 500 (WA).....	661
Tylactin RTD(QH).....	821	VALSARTAN.....	144
TYR Anamix infant(SB).....	816	VALSARTAN + HYDROCHLOROTHIAZIDE.....	149

<i>Valsartan/Amlodipine Sandoz 80/5 (NM)</i> .....	150	<i>VISMODEGIB</i> .....	341
<i>Valsartan/Amlodipine/HCT Sandoz 160/5/12.5 (NM)</i> .....	152	<i>Vistil Forte(AE)</i> .....	780, 781
<i>Valtrex(RW)</i> .....	277, 278, 913, 1151	<i>Vistil(AE)</i> .....	780, 781
<i>Vancocin(AS)</i> .....	55	<i>Visudyne(NV)</i> .....	772
<b>VANCOMYCIN</b>		<i>Vita-B12 (GH)</i> .....	112
<b>.ALIMENTARY TRACT AND METABOLISM</b> .....	55	<i>Vita-B12(GH)</i> .....	1649
<b>.ANTIINFECTIVES FOR SYSTEMIC USE</b> .....	262	<b>VITAMINS, MINERALS AND TRACE ELEMENTS</b>	
<i>Vancomycin Alphapharm (AF)</i>		<b>FORMULA</b> .....	825
<b>.ANTIINFECTIVES FOR SYSTEMIC USE</b> .....	262, 263	<b>VITAMINS, MINERALS AND TRACE ELEMENTS WITH</b>	
<i>VARDENAFIL</i> .....	1659	<b>CARBOHYDRATE</b> .....	825, 826
<i>VARENICLINE</i> .....	729, 730	<i>VitA-POS(AE)</i> .....	779
<i>Vasafil 100 (RW)</i> .....	1659	<i>Volibris(GK)</i> .....	858, 1095
<i>Vasafil 25 (RW)</i> .....	1658	<i>Volirop 12.5(DO)</i> .....	127
<i>Vasafil 50(RW)</i> .....	1659	<i>Volirop 25(DO)</i> .....	127
<i>Vascalace 1.25 (DO)</i> .....	136	<i>Volirop 3.125 (DO)</i> .....	128
<i>Vascalace 10(DO)</i> .....	136	<i>Volirop 6.25(DO)</i> .....	127
<i>Vascalace 2.5 (DO)</i> .....	136	<i>Voltaren 100(NV)</i> .....	610, 831
<i>Vascalace 5 (DO)</i> .....	137	<i>Voltaren 25(NV)</i> .....	611, 832
<i>Vascalace Caps 1.25(DO)</i> .....	136	<i>Voltaren 50(NV)</i> .....	610, 611, 832
<i>Vascalace Caps 10(DO)</i> .....	135	<i>Voluven 6%(PK)</i> .....	112
<i>Vascalace Caps 2.5 (DO)</i> .....	136	<b>VORICONAZOLE</b> .....	269, 270, 271
<i>Vascalace Caps 5 (DO)</i> .....	137	<i>Voriconazole APOTEX (TX)</i> .....	270
<i>Vasocardol (AV)</i> .....	131	<i>Voriconazole Sandoz(SZ)</i> .....	270
<i>Vasocardol CD (AV)</i> .....	131	<b>VORINOSTAT</b> .....	342, 343
<i>Vedafil (AF)</i> .....	1659	<i>Votrient(NV)</i> .....	325, 326, 327
<i>Vedafil(AF)</i> .....	1658, 1659	<i>Voxam (SZ)</i> .....	706
<i>Vedilol 12.5 (RW)</i> .....	127	<i>Vttack (AF)</i> .....	270
<i>Vedilol 25 (RW)</i> .....	127	<i>Vycin IV(EA)</i> .....	262, 263
<i>Vedilol 3.125(RW)</i> .....	128	<i>Vytorin(MK)</i> .....	180, 183
<i>Vedilol 6.25 (RW)</i> .....	127	<i>Vyvanse(ZI)</i> .....	716
<b>VEDOLIZUMAB</b> .....	948, 952, 1186, 1190	<i>Vzole(RW)</i> .....	270, 271
<i>Veletri(AT)</i> .....	873, 1110	<b>WARFARIN</b> .....	93
<i>Velphoro(FN)</i> .....	785, 1078, 1317	<i>Wartec Cream(GK)</i> .....	1654
<b>VEMURAFENIB</b> .....	337	<i>Waxsol(HM)</i> .....	1673
<i>Venla RBX (RA)</i> .....	712	<i>Wellvone(AS)</i> .....	733
<b>VENLAFAXINE</b> .....	712	<b>WHEY PROTEIN FORMULA SUPPLEMENTED WITH</b>	
<i>Venlafaxine AN SR(EA)</i> .....	712, 713	<b>AMINO ACIDS, LONG CHAIN POLYUNSATURATED</b>	
<i>Venlafaxine generichealth XR (GQ)</i> .....	712, 713	<b>FATTY ACIDS, VITAMINS AND MINERALS, LOW IN</b>	
<i>Venlafaxine Sandoz XR(SZ)</i> .....	712, 713	<b>PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE</b>	
<i>Venofer(AS)</i> .....	111	.....	826
<i>Ventavis(BN)</i> .....	878, 1115	<b>WHEY PROTEIN FORMULA SUPPLEMENTED WITH</b>	
<i>Ventolin CFC-free(GK)</i> .....	26, 737	<b>AMINO ACIDS, VITAMINS AND MINERALS, AND LOW</b>	
<i>Ventolin Nebules(GK)</i> .....	26, 737	<b>IN PROTEIN, PHOSPHATE, POTASSIUM AND</b>	
<i>Ventolin Rotacaps(GK)</i> .....	737	<b>LACTOSE</b> .....	826
<i>Ventolin(GK)</i> .....	747	<b>WOOL ALCOHOLS</b> .....	1652
<i>Vepesid(BQ)</i> .....	288	<i>Xalacom(PF)</i> .....	761, 762
<b>VERAPAMIL</b> .....	130	<i>Xalamol 50/5 (QA)</i> .....	761, 762
<b>VERTEPORFIN</b> .....	771	<i>Xalaprost (QA)</i> .....	761
<b>VESPULA SPP VENOM</b> .....	783	<i>Xalatan(PF)</i> .....	761
<i>Vexazone (AF)</i> .....	79	<i>Xalkori(PF)</i> .....	295
<i>Vexazone(AF)</i> .....	79, 80	<i>Xarelto(BN)</i> .....	107, 108, 109
<i>Vfend(PF)</i> .....	269, 270, 271	<i>Xatral SR(SW)</i> .....	1660
<i>Viagra (PF)</i> .....	1659	<i>Xelabine (QA)</i> .....	287
<i>Viagra(PF)</i> .....	1659	<i>Xelabine(QA)</i> .....	287
<i>Vidaza(CJ)</i> .....	919, 1156, 1157	<i>Xeljanz(PF)</i> .....	370, 375
<i>Videx EC(BQ)</i> .....	1324	<i>Xelocitabine (JU)</i> .....	287
<i>Viekira Pak(VE)</i> .....	280, 916, 1153	<i>Xelocitabine(JU)</i> .....	287
<i>Viekira Pak-RBV(VE)</i> .....	281, 916, 917, 1154	<i>Xeloda(RO)</i> .....	287
<b>VIGABATRIN</b> .....	661	<i>Xenical(RO)</i> .....	1647
<b>VILDAGLIPTIN</b> .....	84	<i>Xeomin(EZ)</i> .....	1347
<b>VILDAGLIPTIN + METFORMIN</b> .....	76	<i>Xergic(AF)</i> .....	1672
<i>Vimpat(UC)</i> .....	663, 664, 665	<i>Xgeva(AN)</i> .....	629
<b>VINORELBINE</b> .....	287	<i>Xifaxan(NE)</i> .....	55
<i>Viramune (BY)</i> .....	1330	<i>Xigduo XR 10/1000(AP)</i> .....	69
<i>Viramune XR (BY)</i> .....	1329	<i>Xigduo XR 10/500(AP)</i> .....	69
<i>Viramune(BY)</i> .....	1329	<i>Xigduo XR 5/1000(AP)</i> .....	69
<i>Viread(GI)</i> .....	1327	<b>XLYS, LOW TRY Maxamum(SB)</b> .....	812
<i>Viscopaste 4948(SN)</i> .....	1678	<b>XMET Maxamum(SB)</b> .....	812
<i>Viscotears Gel PF(IV)</i> .....	773	<b>XMTVI Maxamum(SB)</b> .....	813
<i>Viscotears(IV)</i> .....	773	<i>Xolair(NV)1059, 1060, 1066, 1070, 1298, 1299, 1305, 1309</i>	

<i>XP Maxamaid(SB)</i> .....	814	<i>.Repatriation Pharmaceutical Benefits Scheme</i> .....	1661
<i>XP Maxamum(SB)</i> .....	814	<i>Zithromax (PF)</i>	
<i>XPhen, Tyr Maxamum(SB)</i> .....	816	<i>.ANTIINFECTIVES FOR SYSTEMIC USE</i> .....	254
<i>Xtandi(LL)</i> .....	350	<i>.SENSORY ORGANS</i> .....	750
<i>Xylocaine Viscous(QA)</i> .....	1653	<i>Zithromax(PF)</i>	
<i>Xylocard 500(AS)</i> .....	114	<i>.Highly Specialised Drugs Program (Private Hospital)</i>	912
<i>Yomax 250(DO)</i> .....	237	<i>.Highly Specialised Drugs Program (Public Hospital)</i>	1149
<i>Yomax 500 (DO)</i> .....	237	<i>Zithromax(PF)</i>	
<i>Z.S.C.(RW)</i> .....	1657	<i>.ANTIINFECTIVES FOR SYSTEMIC USE</i> .....	254
<i>Zabep (AL)</i> .....	41	<i>.SENSORY ORGANS</i> .....	750
<i>Zactin Tablet (AF)</i> .....	706	<i>Zitrocin(GN)</i> .....	1661
<i>Zactin(AF)</i> .....	706	<i>Zocor (MK)</i> .....	164, 165, 166
<i>Zan-Extra 10/10(GO)</i> .....	139	<i>Zofran (AS)</i> .....	45
<i>Zan-Extra 10/20(GO)</i> .....	139	<i>Zofran syrup 50 mL(AS)</i> .....	45, 46
<i>Zanidip(GO)</i> .....	129, 130	<i>Zofran Zydys(AS)</i> .....	46, 47
<i>Zantac Syrup(AS)</i> .....	34	<i>Zofran(AS)</i> .....	45
<i>Zantac(AS)</i> .....	34, 35	<i>ZolaCos CP 10.8/50(28)(AP)</i> .....	345
<i>Zarontin(IX)</i> .....	657	<i>ZolaCos CP 10.8/50(84)(AP)</i> .....	344
<i>Zarzio(SZ)</i> .....	924, 1162	<i>ZolaCos CP 3.6/50(AP)</i> .....	345
<i>Zatamii(EO)</i> .....	202, 203, 204	<i>Zoladex 10.8 Implant(AP)</i> .....	344
<i>Zavedos(PF)</i> .....	288	<i>Zoladex Implant(AP)</i> .....	344
<i>Zedace(AF)</i> .....	131, 132	<i>Zoledasta(TX)</i> .....	624
<i>Zedd 500(RW)</i> .....	1661	<i>ZOLEDRONIC ACID</i> .....	623, 624, 1052, 1290
<i>Zeffix(RW)</i> .....	1326	<i>Zolinza(MK)</i> .....	343
<i>Zelboraf(RO)</i> .....	337	<i>ZOLMITRIPTAN</i> .....	655
<i>Zeldox (PF)</i> .....	679, 680	<i>Zoloff(PF)</i> .....	707, 708
<i>Zelitrex (RF)</i> .....	277, 278	<i>Zoltrip (RW)</i> .....	656
<i>Zelitrex(RF)</i> .....	277, 278	<i>Zomacton(FP)</i> .....	1364, 1414, 1431
<i>Zentel(AS)</i> .....	734	<i>Zometa(NV)</i> .....	1052, 1291
<i>Zepatier(MK)</i> .....	279, 915, 1152	<i>Zomig(AP)</i> .....	656
<i>Zerit(BQ)</i> .....	1326	<i>Zonegran (SA)</i> .....	670
<i>Zestril(AP)</i> .....	133	<i>ZONISAMIDE</i> .....	670
<i>ZETIN(RW)</i> .....	193	<i>ZOPICLONE</i> .....	1669
<i>Zetlam(AF)</i> .....	1326	<i>Zopiclone GH(GQ)</i> .....	1669
<i>Ziagen(VI)</i> .....	1323	<i>Zopral ODT(AF)</i> .....	37
<i>ZIDOVUDINE</i> .....	1328	<i>Zopral(AF)</i> .....	37, 38
<i>Zilarex(SZ)</i> .....	1671	<i>Zoton FasTabs(PF)</i> .....	37
<i>Zilfojim 4 (DO)</i> .....	45	<i>Zovirax 200 mg(GK)</i> .....	273
<i>Zilfojim 8 (DO)</i> .....	45	<i>Zovirax(GK)</i> .....	751
<i>Zilfojim ODT 4(DO)</i> .....	47	<i>ZUCLOPENTHIXOL DECANOATE</i> .....	680
<i>Zilfojim ODT 8(DO)</i> .....	47	<i>Zumenon(GO)</i> .....	214
<i>Zimstat (AF)</i> .....	164, 165, 166	<i>Zyban(AS)</i> .....	727, 728
<i>Zinbryta(BD)</i> .....	544	<i>Zydelig(GI)</i> .....	338, 339
<i>ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + PURIFIED TALC</i> .....	1657	<i>Zydol SR 100 (RW)</i> .....	648
<i>ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE</i> .....	1650	<i>Zydol SR 150(RW)</i> .....	647
<i>Zinnat (AS)</i> .....	250	<i>Zydol SR 200(RW)</i> .....	648
<i>Zinnat(AS)</i> .....	249, 250	<i>Zydol(RW)</i> .....	648, 649
<i>Zinopril 10(AL)</i> .....	133	<i>Zykadia(NV)</i> .....	294
<i>Zinopril 20(AL)</i> .....	133	<i>Zyloprim(RW)</i> .....	620
<i>Zinopril 5(AL)</i> .....	133	<i>Zypine ODT(AF)</i> .....	683, 684, 685
<i>ZIPRASIDONE</i> .....	679	<i>Zypine(AF)</i> .....	681, 682, 683
<i>ZIPROX(RW)</i> .....	679, 680	<i>Zyprexa Relprevv(LY)</i> .....	685
<i>ZipZoc 66000747(SN)</i> .....	1678	<i>Zyprexa Zydys(LY)</i> .....	683, 684, 685
<i>Zircol (AF)</i> .....	129, 130	<i>Zyprexa(LY)</i> .....	681, 682, 683
<i>Zithromax (PF)</i>		<i>Zyrtec(JT)</i> .....	1671
		<i>Zytiga(JC)</i> .....	353